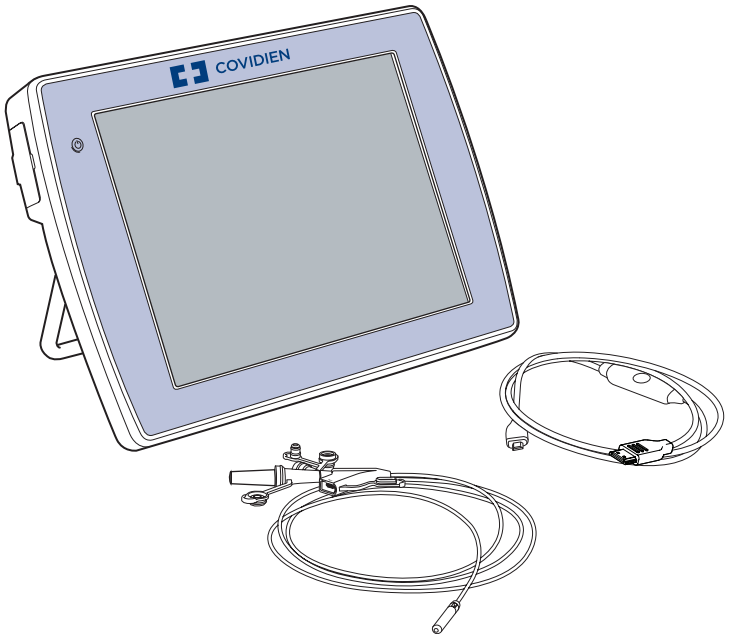
COVIDIEN

User Manual

Kangaroo™

Console



For use with Kangaroo™ Feeding Tubes with IRIS Technology

Table of Contents

Section I: System Overview

Safety and Cautions 2
System Components 3

Section II: Assembly and Initial Administrator Use

Assembling System Parts 9
Initial Use 10

Section III: Setting Up and Using the Kangaroo Feeding Tube with IRIS Technology for Placement

Set Up and Use 13
Reconnecting 17

Section IV: Cleaning, Charging, and Storage

General Console and Power Cord Cleaning Directions 19
Battery and Storage 20

Section V: User Interface Features

On Screen Keyboard 22
Logging In and Automatic Log-Out 23
Main Menu 24
Procedure 25
Options for Viewing Patient Folders and Files 26
Exporting Images to USB Flash Drive 27
Opening Images from USB Flash Drive 28
Rename Images 29
Delete Images 29
Viewing Captured Images 30
Annotating Images 31
Operator and Reviewer Settings 32
Administrator Settings 33
Changing Date, Time, Formatting, Language, and Device Settings 34
Adding and Editing Users 35
Creating and Editing Encryption Password 36
Icon Glossary 37

Section VI: Additional Kangaroo Feeding Tube with IRIS Technology Information

Order Information 39
Troubleshooting 40
Definition of Symbols 41
Warranty 42
Specifications 43
MRI Safety Information 43
Maintenance and Safety 44
Electronic Specification Tables 45-49

Section I: System Overview

Safety and Cautions

Safety notice

This section summarizes information basic to the safe operation of the equipment described in this manual. All safety precautions and operating instructions should be read and understood before installation, operation, maintenance, or repair of this device. Consult with Covidien-trained personnel before attempting to operate this equipment. Always follow product labeling and manufacturer's recommendations. If in doubt as to how to proceed in any situation, contact your Covidien representative.

Note: For Enteral Feeding Only

Description

The Kangaroo™ feeding tube with IRIS technology is a single use device with a camera embedded in the distal end to aid in placement. The tube is made of radiopaque polyurethane material and features a Hydromer™* coated tip. The connectors are color coded to provide a visual indicator for enteral use only.

Indications

The Kangaroo feeding tube with IRIS technology utilizes a video stream to aid a trained user during placement into the stomach or small bowel for the administration of nutrition, fluids, and medications by the naso-enteric route for patients aged 18 years and older who have an intact gastrointestinal tract, but are physically unable to manage nutritional intake through normal mastication and deglutition.

A trained user, as defined per facility protocol or determined by clinical privileging, should read the Kangaroo Feeding Tube with IRIS Technology User Manual, Instructions for Use and review the training program provided. Facility protocol for insertion of any feeding tube should also be followed. Placement of the tip of the device into the small bowel should only be attempted by clinicians with expertise in small bowel placement.

Prior to commencing administration, confirm correct tube placement per institutional protocol.

Actions

- Acts as a conduit for food, fluids, and medications to a patient's stomach or small bowel.
- Avoid administration of light sensitive medications while the tube is connected to the interface cable.

Contraindications

- Use caution with patients who have anomalies or diseases of the nose, throat, or esophagus.
- The use of this product is contraindicated in patients with known sensitivities or allergies to its components.

Warnings

- Coughing or any other symptom of respiratory distress would likely indicate that the device had been misplaced in the trachea. If this is suspected, remove the tube and guidewire and reinsert.
- At any point during the procedure if continuous resistance is felt the device should be withdrawn and then reinserted. The operator should discontinue all attempts at placement after repetitive unsuccessful attempts (such as 5 or more) at device placement.
- The presence of an endotracheal device tends to guide the feeding tube into the trachea. Should the feeding tube and guidewire (if guidewire is used) enter the tracheobrochial tree during tube placement, damage to the lung or esophagus could occur. If any resistance is felt during placement, remove the tube and guidewire and reinsert. Coughing or any other symptom of respiratory distress would likely indicate that the device had been misplaced in the trachea. Misplacement of tubes into the lungs resulting in pneumothorax has been reported in neurologically impaired patients and those with endotracheal tubes in place. The operator should discontinue all attempts at placement after repetitive unsuccessful attempts (such as 5 or more) at device placement.
- This device should only be inserted by a trained user.
- The feeding tube is a disposable device intended for single use. Do not reuse.
- Maintaining the patient in a High-Fowlers or Semi-Fowlers position may reduce regurgitation or aspiration. If using this position, do not lean patient forward.
- The stylet must be removed prior to a patient MRI.
- No modification of this equipment is allowed.
- Do not use this device near flammable anesthetics or in oxygen rich environments.
- There is a possibility of misconnection of the feeding tube connector and insufflation device connector with the following types of connectors: the sockets of anesthetic and respiratory equipment, conical oxygen tubing, connectors for breathing systems and driving gas applications, and conical connectors for limb cuff inflation applications. The feeding tube is specifically for the purpose of enteral feeding. The insufflation device is for use with the viewing system for connection with the feeding tube during placement, and is to be disconnected from the feeding tube after placement. Please avoid connection of these devices to devices of other applications and ensure that the tubing is appropriately connected in order to provide enteral nutrition to the patient.
- Additional components or equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards. All configurations shall comply with the requirement for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3Ed. of IEC 60601-1, respectively). If the operator connects additional components or equipment to the medical electrical equipment, the operator configures a medical system, and it is the operator's responsibility that the system complies with the requirements for medical electrical systems. If in doubt, consult your local representative or the technical service department.
- When light is emitted from tube tip, do not point directly at eye.
- To minimize heat exposure of tissue, the Kangaroo feeding tube with IRIS technology should be disconnected from the interface cable after the placement is complete.

Precautions

- This device is not intended for diagnosis. Consult the appropriate service for diagnostic evaluation if there is concern regarding an image observed during placement.
- The user should be aware of patients who have photosensitivity due to administered medications or other conditions since the device exposes internal tissues to light.
- Do not autoclave.
- Feeding tubes should be flushed frequently to prevent clogging. Suggested flushing schedule:
  a) before and after each feeding
  b) before and after administering medication
  c) once every four hours during continuous feeding or between intermittent feedings
  d) each time the feeding set is disconnected
  e) each time the feeding container is filled/changed
  f) each time the pump is stopped
- Use only tap or sterile water to flush. Do not use solutions containing meat tenderizer to flush or open a clogged feeding tube.
- Tube replacement may be considered at four (4) week intervals to ensure optimum tube patency.
- Use a Kangaroo™ enteral feeding pump for accuracy and control of nutritional formula delivery. Infusion pumps that deliver in excess of 40 psi should not be used as excessive pressure is capable of causing tubes and pump sets to balloon and/or rupture. Consult pump manufacturer's specifications and recommendations.
- Administration of medications should be guided by hospital policy. Many liquid preparations contain Sorbitol™* which tends to interact with enteral formulas and clog the feeding tube. Thoroughly crush tablets, excluding enteric tablets which should never be crushed; however, always consult with your pharmacist regarding which tablets should be crushed for feeding tube administration.
- The device generates light, the user should be aware of patients who have taken light sensitive medications or who may have photosensitivity.
- Images from the camera going to the console may be lost or temporarily suspended during placement if performed near sources of electromagnetic energy such as RFID, diathermy equipment or hand-held metal detectors.

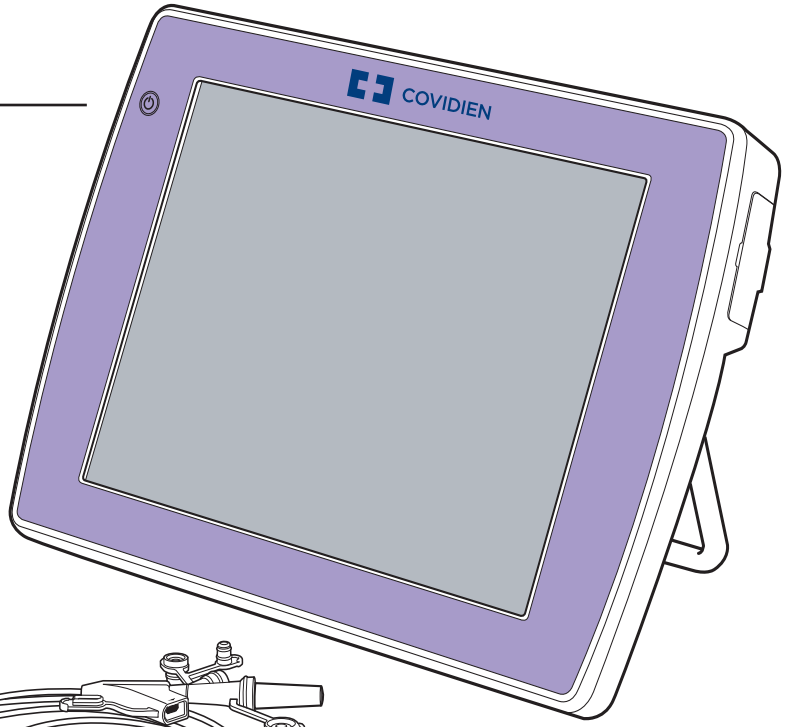
Adverse events

Pneumothorax, intestinal perforation, and aspiration pneumonia have been reported during the use of this type of device.

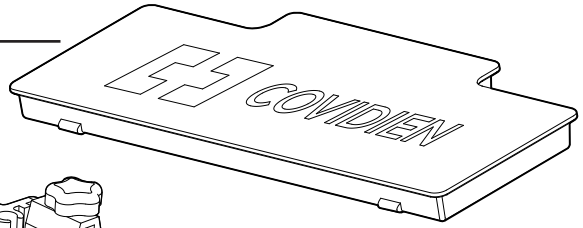
System Components

The Kangaroo feeding tube with IRIS technology is supplied in a semi-ready-to-use state.

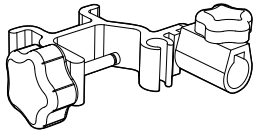
Console with touch screen interface



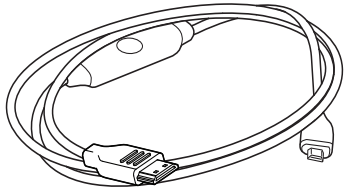
Rechargeable battery



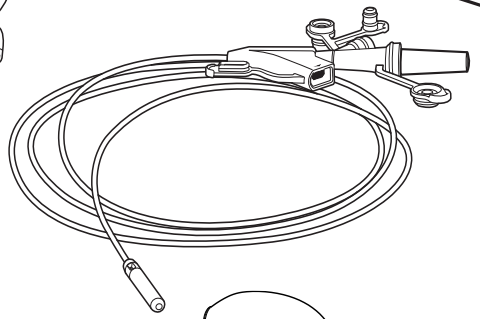
Mounting clamp



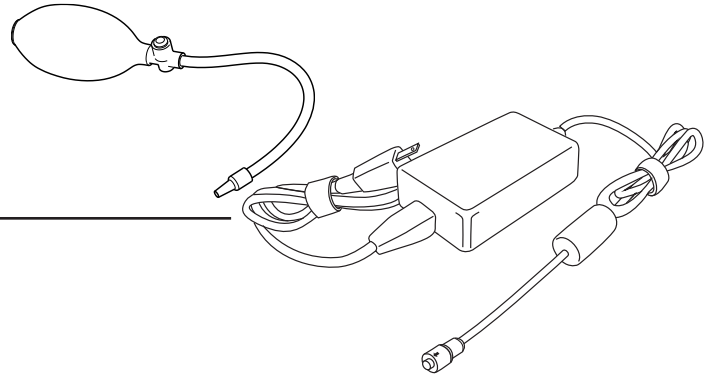
Interface cable



Kangaroo feeding tube with IRIS technology and stylet
(packaged separately)



Insufflation device (packaged separately)

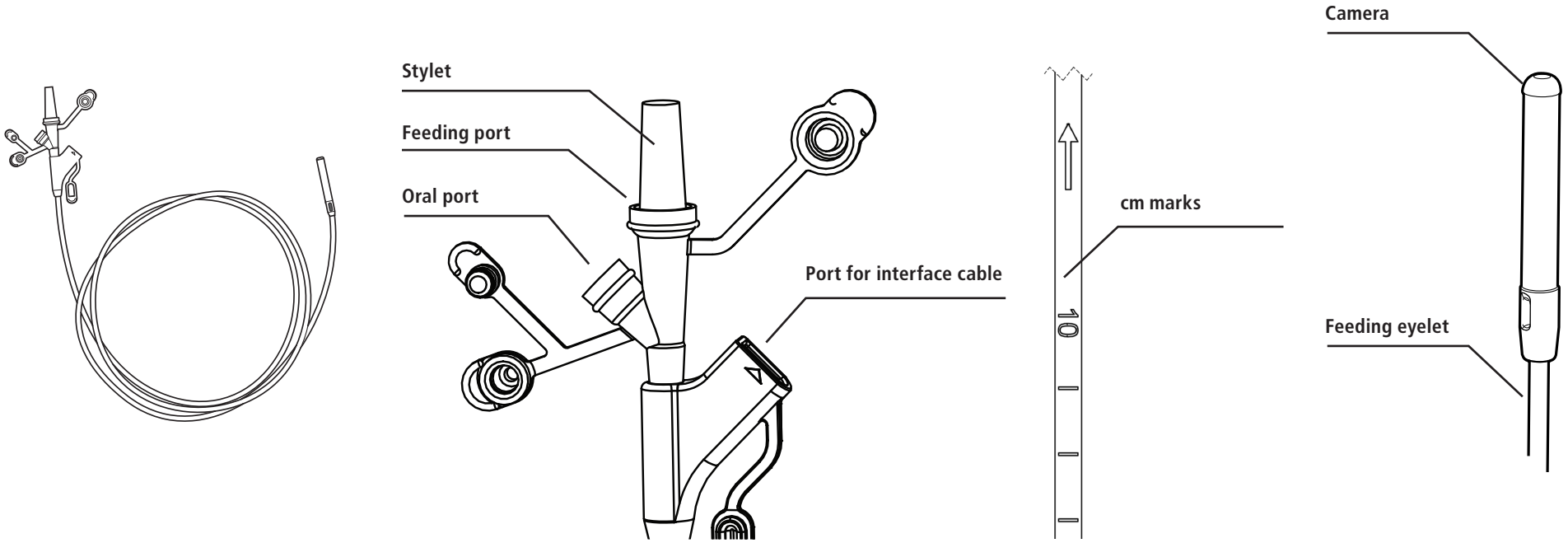


Detachable power adapter

Optional accessories (see section regarding optional accessories):
Battery charging station, mounting cart, and carrying case.

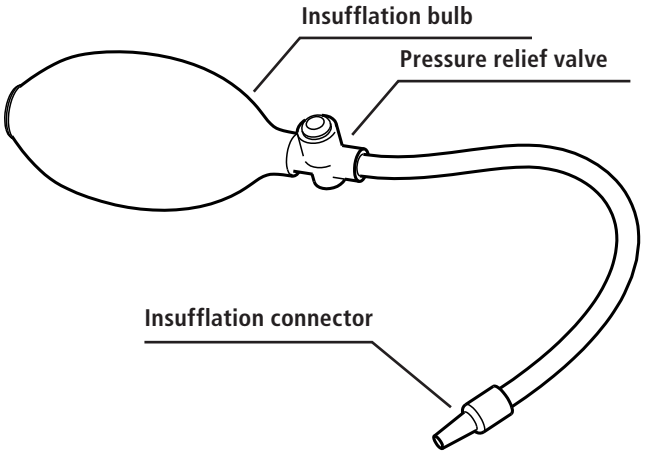
Kangaroo Feeding Tube with IRIS Technology and Stylet (single use devices):

The Kangaroo feeding tube with IRIS technology and stylet is a single use device with a camera embedded in the distal end to aid in placement. The tube is made of radiopaque polyurethane material and features a Hydromer coated tip.

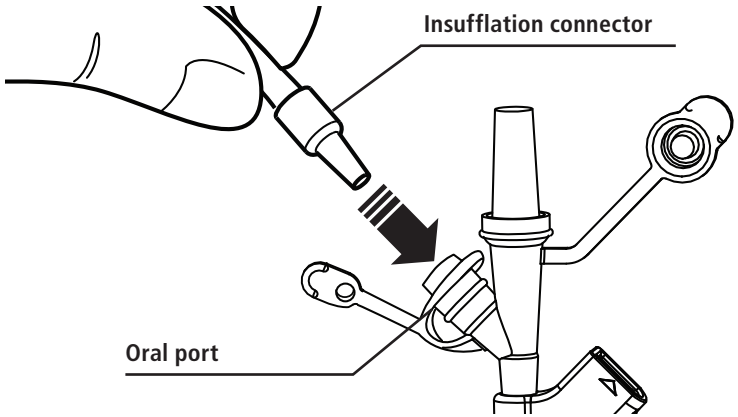


Insufflation device (single use device):

The insufflation device is included to aid in feeding tube placement.

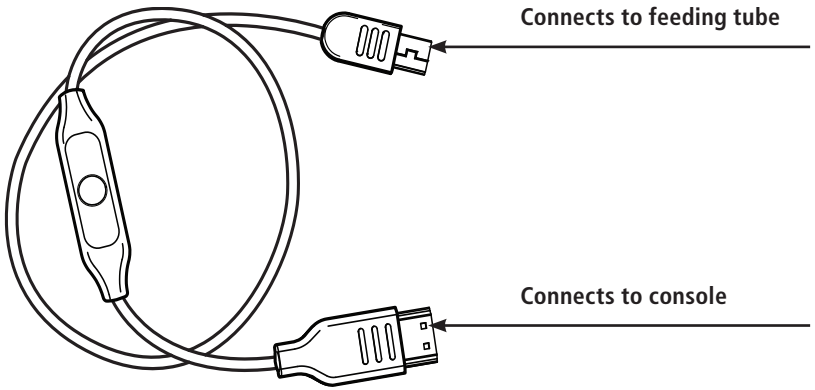


The insufflation device is connected to the feeding tube through the oral port.

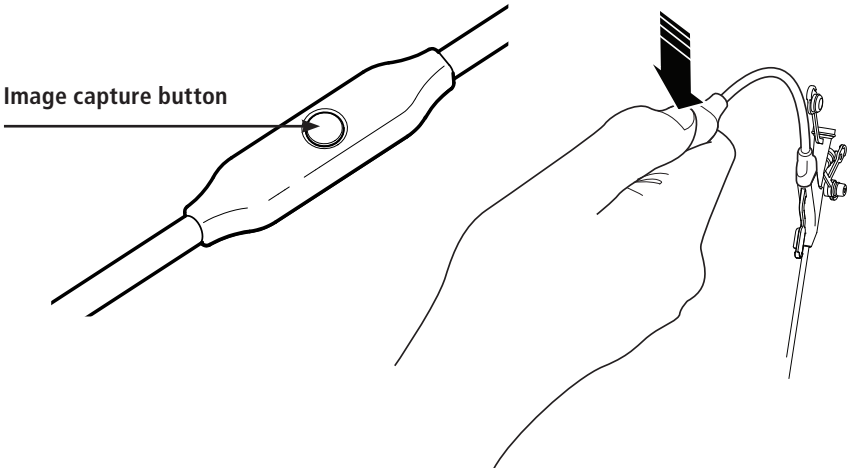


Interface cable:

The interface cable is a re-usable cable that connects the console to the tube.

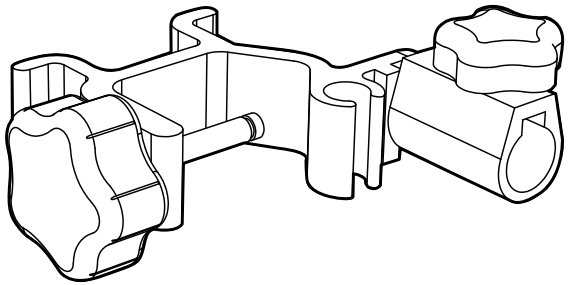


The interface cable has a push-button used to capture images of the procedure.



Mounting clamp:

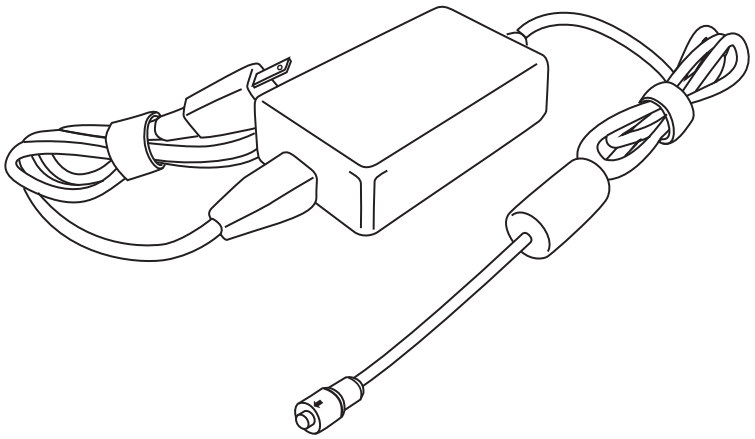
The mounting clamp is used to attach the console to a pole, if desired. For detailed instructions, refer to the assembly section.



Power adapter:

The power adapter is supplied with five AC power cord options. Plug the power adapter into the console to charge the battery.

It is important to choose the appropriate AC power cord for your region.



Console and battery:

The console has a full-color touch screen that displays a real time image as the feeding tube travels through the patient during the placement procedure. Images can be captured, stored, and annotated on the console.

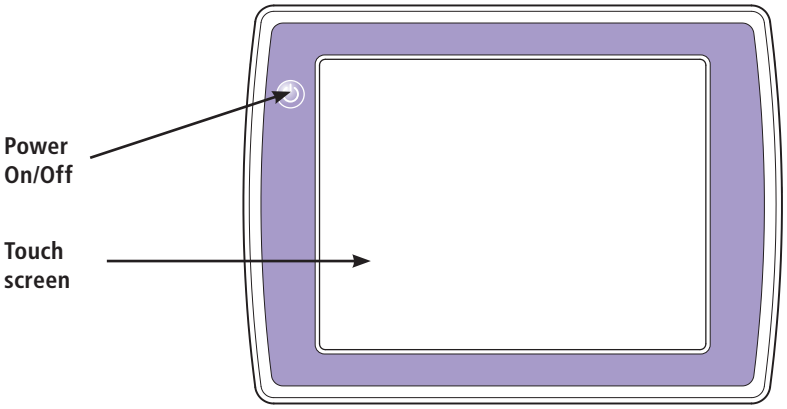
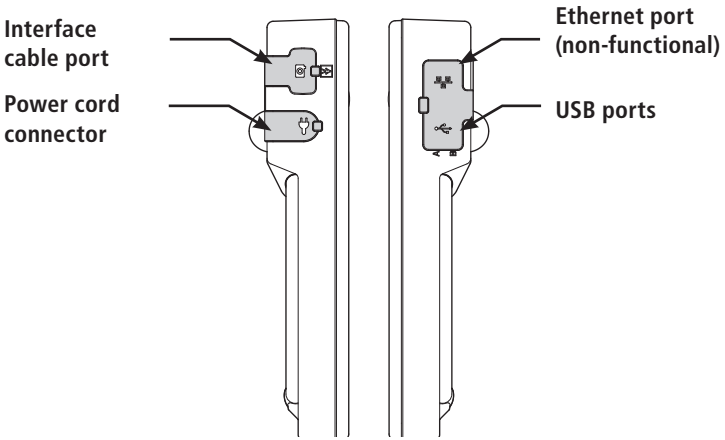


Image capture:

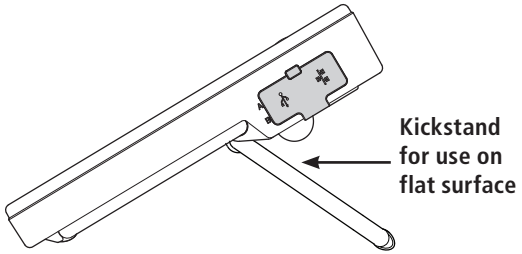
The console has security features to help protect the information from being accessed by other people. The device requires a login name and password to use the system. Stored images can be exported as .bmp or .jpg files onto a USB flash drive and added to a patient's file. Images are password-protected for security and privacy purposes.

The USB ports are also used for software updates to the system.



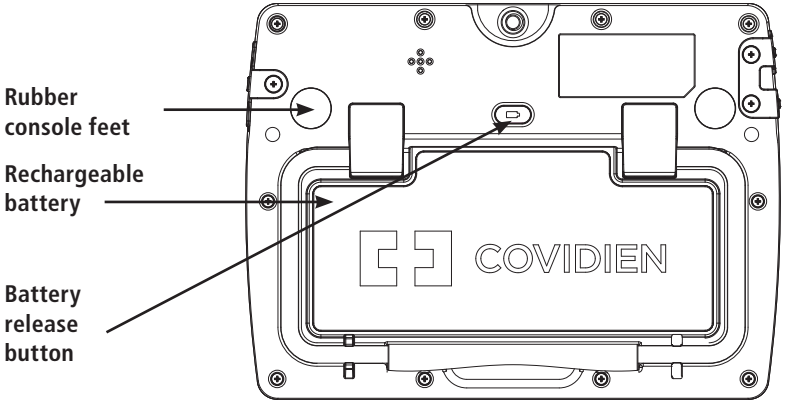
Kickstand:

The console can be used on a tabletop or mounted on a pole or cart. A built-in kickstand props the console up at an ideal viewing angle when on a flat surface.



Rechargeable battery:

A replaceable, rechargeable Li-Ion battery is included. The console recharges when the power adapter is plugged in to an AC outlet, or by using the battery charger (optional accessory).



Mounting clamp:

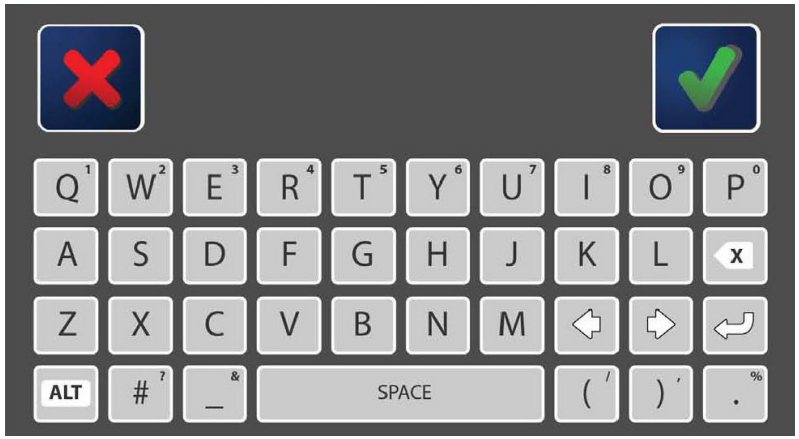
The mounting clamp can be attached to the back of the console and is easily removable. For information on attaching, using, and removing the mounting clamp, see section regarding assembly.

Console user interface:

The console has a color-display touch screen with step-by-step prompts to guide you through setup and operation.

On screen keyboard:

An on screen keyboard will appear when typing is necessary. Use the keyboard to enter text, such as a login name, patient information, or to annotate images.

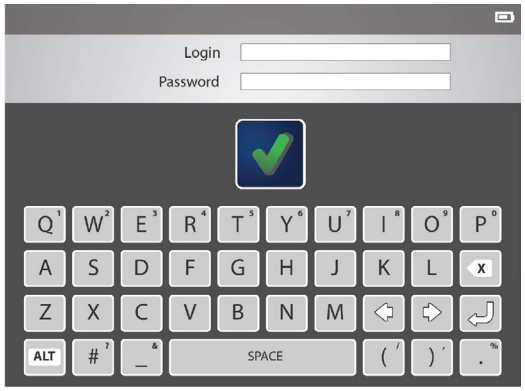


To enter text:	Tap a text field (such as a login name or password) and then use the on screen keyboard to type.
To edit text:	Tap the text field and use the arrow keys to navigate to desired text location.
To enter numbers or secondary symbols:	Press the ALT key. Tap the key(s) that contains the desired number or symbol (displayed in the upper, right corner). When finished, press the ALT key again.

When finished typing, press the check mark icon to save or the to cancel and return to the previous screen.

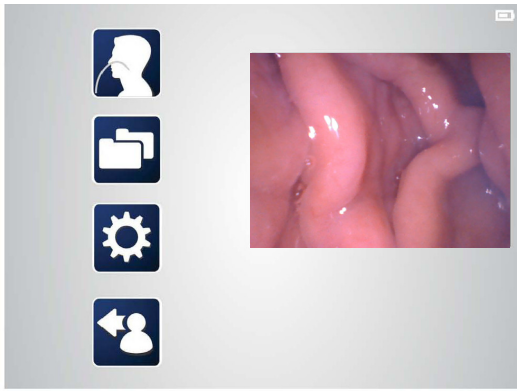
System login:

After the initial set up, users will be prompted for a login name and password to access the system. First time users should receive their login information from an administrator. After logging in, the screen will show the main menu.



Main menu:

The main menu provides links to log out, settings, file management, and procedure initiation. Clicking any of these icons brings you to those screens.



Procedure:

Use the procedure feature to launch the functional flow for entering patient information and procedure activities.

Folders menu:

The folders menu launches the data browser of patient folders. Each folder contains images captured during the procedure.

Settings menu:

The settings menu provides links to modify language, date/time, file formats, passwords, device options, and user settings.

Log out:

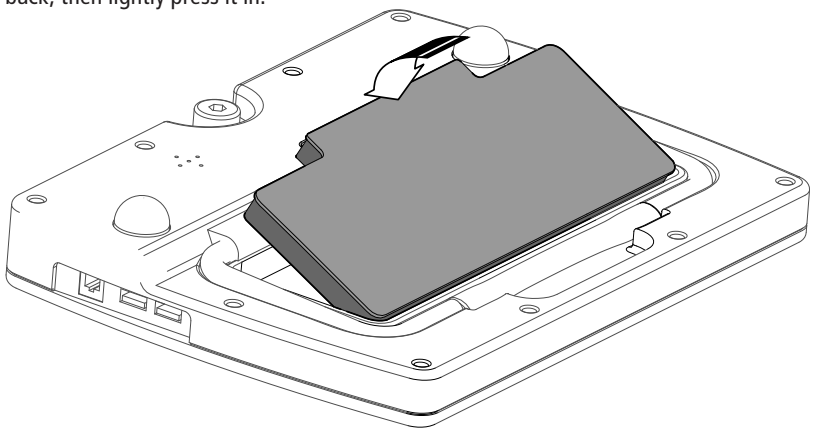
Clicking the log out icon ends the session.

Section II: Assembly and Initial Administrator Use

Assembling System Parts

Attach battery:

The battery provided is both removable and rechargeable. To place it into the console, align it with the space on the back, then lightly press it in.

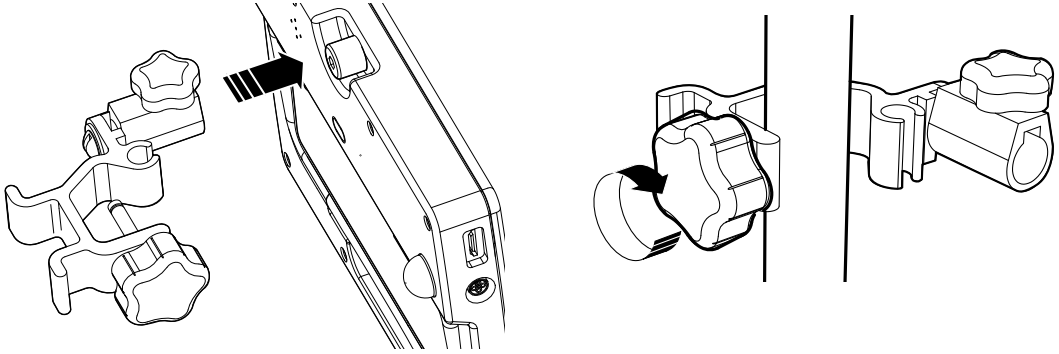


Attach mounting clamp (optional):

The console can be attached to a vertical pole using the mounting clamp, included with the system components.

Attach the clamp to the console by aligning the hole on the pole clamp with the mounting hole on the back of the console. Use a 3/8" - 16 bolt to fasten together.

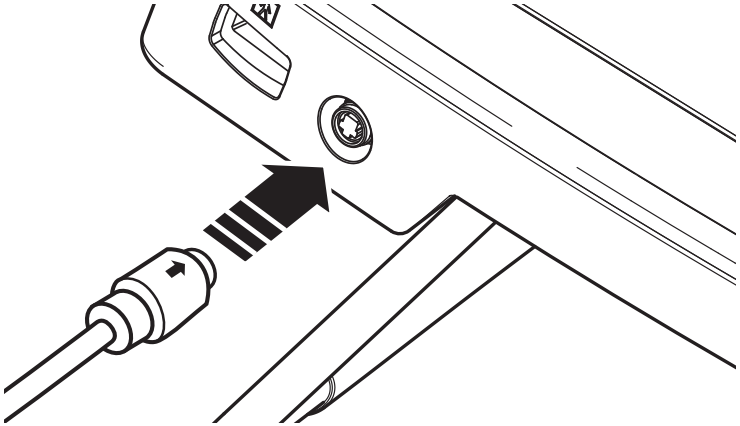
Attach the mounting clamp to a pole by fitting it in between. Then, tighten the knob so that the clamp and console are securely attached.



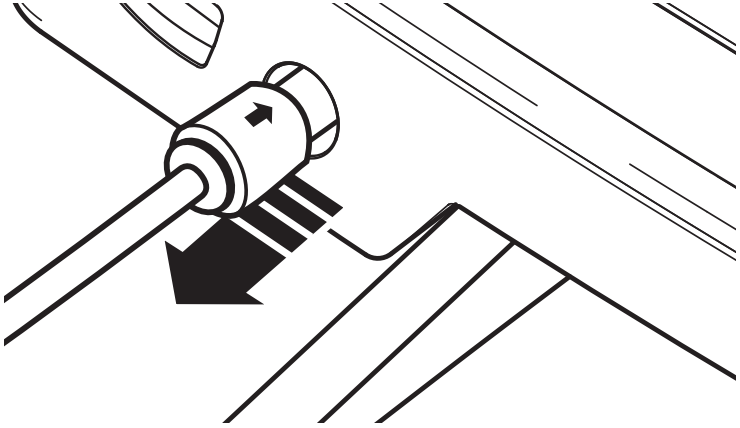
Connecting power adapter:

The removable power adapter connects to the console to charge the battery.

To connect, arrow on power adapter should be facing up (same side as screen).



To disconnect, grasp cord by the locking sleeve and pull away from console.



Initial Administrator Use

When the console is powered on for the first time, or after being reset to factory settings, the administrator account needs to set up the console settings.

Choose language:

Choose the language for the console interface.

Administrator password:

Create a password that will be used only for the system administrator account. Use the on screen keyboard to enter the password into the text fields. The password must be between 8 and 12 characters. Password can include uppercase letters, numbers, and symbols.

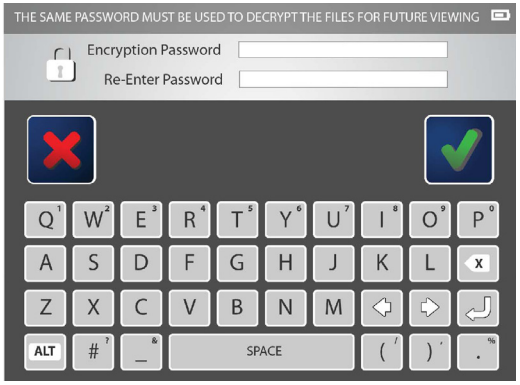
This administrator login name is "ADMINISTRATOR". Other administrator accounts can be created in addition to this.

Encryption password:

The password created will be needed to open any files exported from this console. The same password will be used for any files exported.

Tap on the first text field to enter the desired password. Then, re-enter the password in the text field below. When satisfied, touch the check mark to save the changes.

Note: The password is case-sensitive and will be in all upper-case.



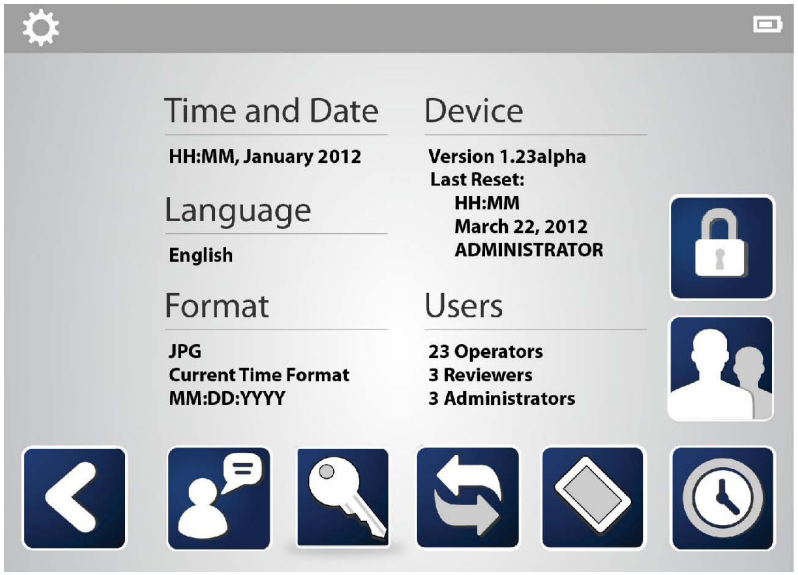
Initial Administrator Use

When the console is powered on for the first time, or after being reset to factory settings, the administrator account needs to set up the console settings. A settings menu will appear once the language preference, administrator password and encryption password have been set.

Settings menu:

Tap on the icons at the bottom of the screen to make changes to the date/time, language, file format, device, and users.

It is recommended that the current time and date is set prior to use. New user logins and passwords should be added at this point.



Back:
Return to previous screen.

Time and date:
Set or change the time and date.

Language:
Change the preferred language.

Format:
Choose the preferred image type (.jpg or .bmp) for export.
Edit the way the time and date are written on the patient files and images.

Device:
Erase patient data, update software, or reset console back to factory settings.

Password:
Change the login password.
Passwords must be reset after 90 days.

User groups:
Create logins and passwords for operators and reviewers.
Change login names and/or passwords for other users.

Encryption password:
Create password to decrypt and open exported files.

Section III: Setting Up and Using the Kangaroo Feeding Tube with IRIS Technology for Placement

Set Up and Use

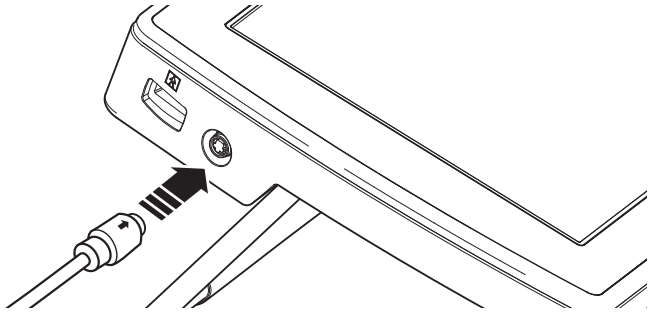
1. **Read all warnings and precautions prior to tube insertion.**
2. **Explain procedure to the conscious patient. Prepare supplies (oral tip syringe, feeding tube water, wipes, and stethoscope).**

Position console in a direct line of sight. Console can be pole mounted, propped on bedside table, or handheld.

CAUTION
Do not place console on patient's bed during procedure.
Check battery life of console. If low, connect console to AC power outlet.

3. **Plug in the power cable (if necessary).**

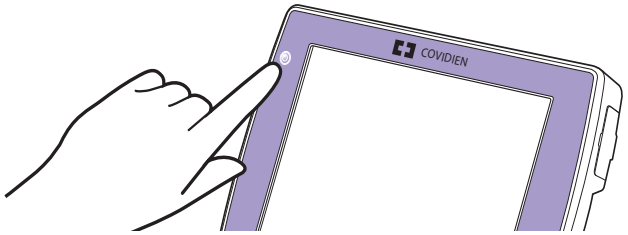
If desired, connect the power cord to the console. To connect, arrow on power adapter should be facing up (same side as screen).



4. **Power the console on.**

Press the power button. The system should start up shortly after and display a login screen.

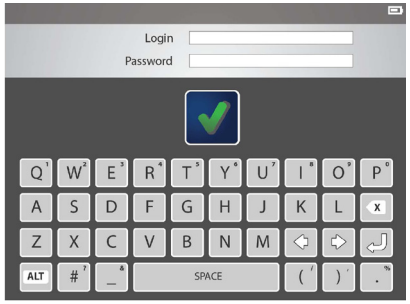
Note: After a period of inactivity (no user input to the console), the console will automatically log the user out. This log-out will not occur during a procedure.



5. **Enter login, password, and patient information.**

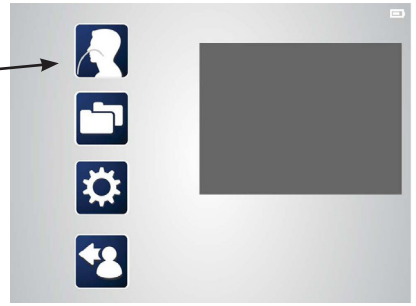
The system will request a login name and password. After typing, tap the check mark to proceed to the main menu.

Note: First time users need to have an administrator set up a login name and password prior to use.

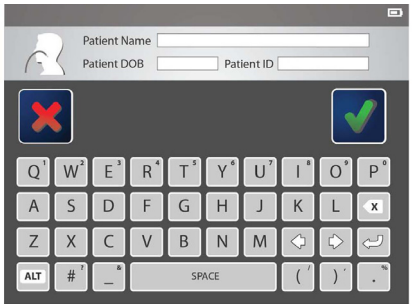


The main menu will appear.

Tap on the procedure icon to begin the placement procedure.



Follow the screen commands to enter the patient information. When complete, tap the check mark to proceed.



The system will ask for confirmation that the information is entered correctly. If yes, tap the check mark. If not, tap the red "x" to go back and re-enter the information.

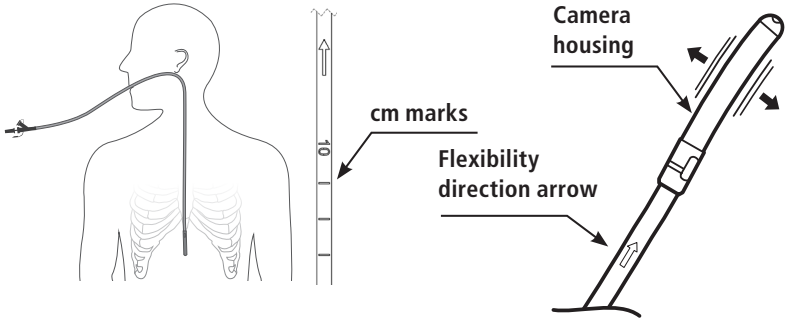
Section III: Setting Up and Using the Kangaroo Feeding Tube with IRIS Technology for Placement

6. Position patient and estimate feeding tube length.

Position patient in accordance with facility protocol for feeding tube placement.

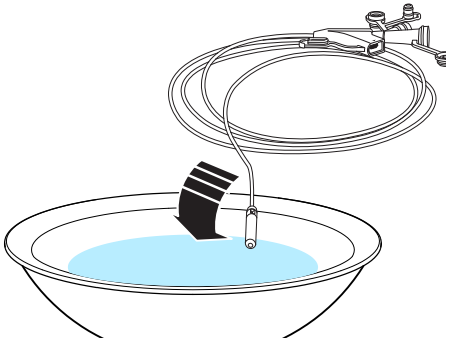
To estimate insertion depth, use the tube to measure the distance from the tip of the patient's nose to the earlobe and from the earlobe to the xiphoid process for gastric placement. Add approximately 10 (ten) inches (25 cm) for intestinal placement. Spontaneous transpyloric passage of the tip often occurs within 24 to 48 hours.

Note: The Kangaroo feeding tube with IRIS technology tip is marked with an arrow on the tube near the feeding eyelets. The tip housing camera has optimal flexibility to bend in two directions, either towards or away from this arrow.



7. Activate Hydromer coating.

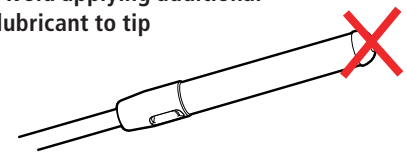
Use water to activate the Hydromer coating on the Kangaroo feeding tube with IRIS technology. Submerge tip for about 5 seconds to activate the Hydromer coating.



CAUTION

If applying lubricant, do not put lubricant on or near the camera-side of the feeding tube. The camera vision may become blocked or blurred.

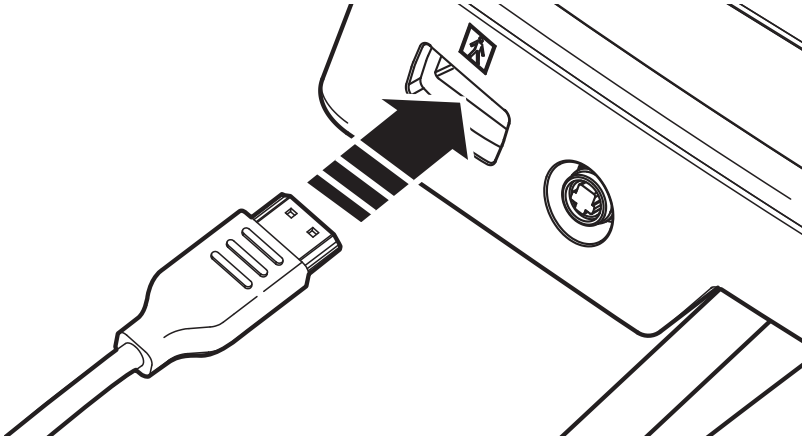
Avoid applying additional lubricant to tip



8. Connect interface cable to console.

After entering patient information, the console will request a feeding tube to be attached.

Start by connecting the larger end of the interface cable to the console.

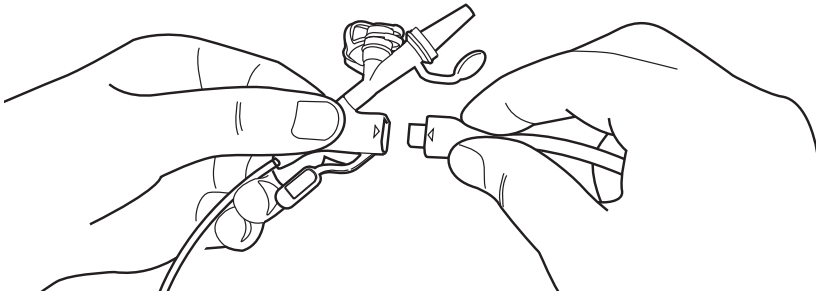


9. Connect interface cable to feeding tube.

A screen on the console will request that a feeding tube be attached. Connect the smaller end of the interface cable to the feeding tube. Once the feeding tube and interface cable are connected to the console, a live feed from the camera will display on the screen.

CAUTION

Allow enough slack so that there is no stress on the tube or console. Strain on the tube or console could cause droppage, breakage, or discomfort to the patient.



10. Choose the most patent nare.

Choose the most patent nare and insert the feeding tube with the stylet. Direct the feeding tube posteriorly, aiming the tip parallel to the nasal septum and superior surface of the hard palate. Advance the tube to the nasopharynx, allowing the tip to seek its own passage. Once in place, do not manipulate or pull the stylet back and forth within the feeding tube. When the tube has reached the oropharnyx, encourage the patient to swallow. Giving sips of cool or room temperature water may assist the passage of the tube.

11. Using the insufflation device.

The insufflation device is for use during placement of the Kangaroo feeding tube with IRIS technology to assist in the identification of anatomical landmarks. Slight distension of the anatomy around the camera's viewing area can aid the visualization of the esophagus and the gastro-intestinal surfaces. Air may be needed for improved viewing of anatomical landmarks when tube tip insertion has progressed beyond the 25-35 cm mark. Additional air may be needed when advanced beyond the esophagogastric (E-G) junction. The volume of air needed for visualization will vary due to the amount of air expelled naturally by the patient during the procedure as well as the distribution of air in the GI tract. Do not administer more air than is necessary for visualization. However, it should be expected that excess air will be expelled naturally from the patient during and after insufflation.

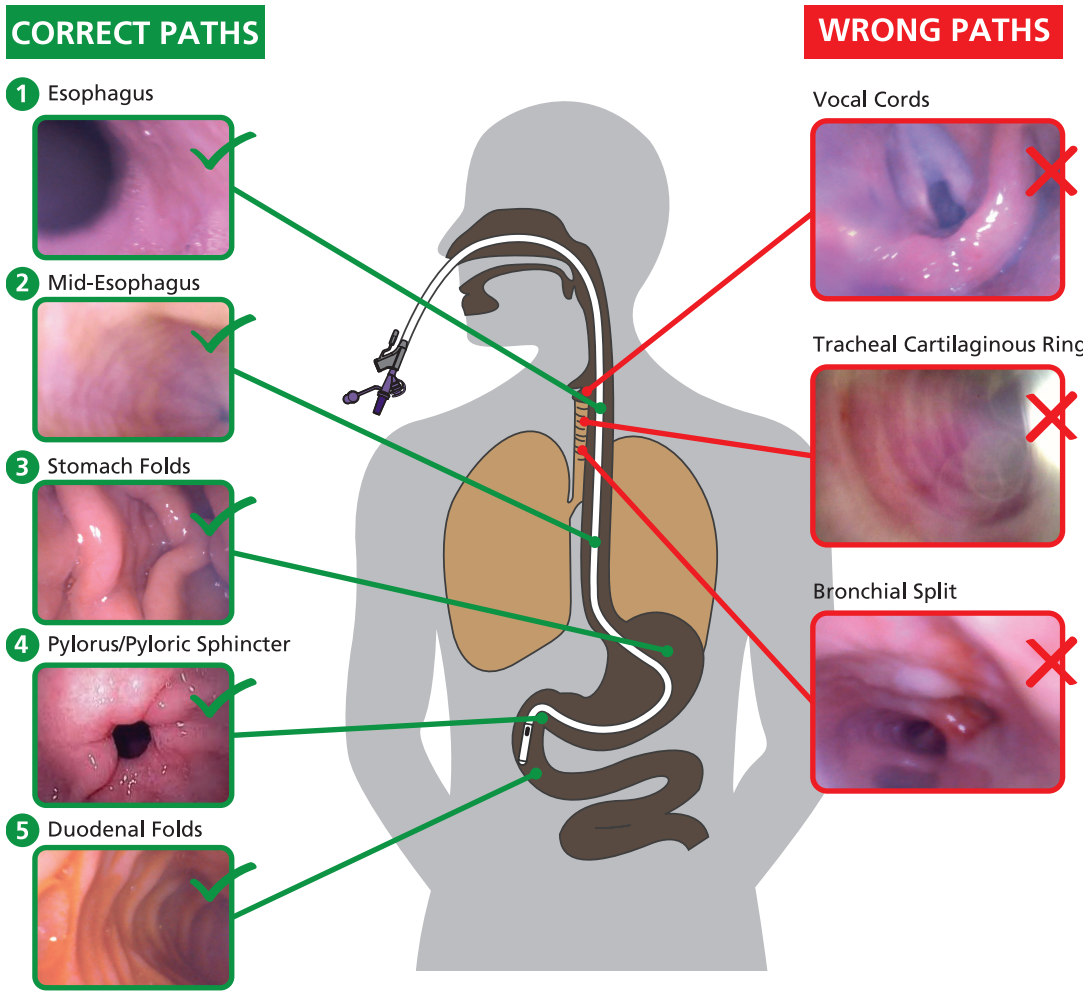
To use the insufflation device, insert the insufflation connector into the oral port of the Kangaroo feeding tube with IRIS technology. The feeding port should be closed off during tube insertion, either by maintaining the stylet hub in the feeding port or by placing the tethered cap into the feeding port. At the discretion of the clinician, air can be delivered through the feeding tube during the placement by manually squeezing the insufflation bulb, which provides approximately 30mL per hand squeeze. Monitor the patient's level of tolerance and visual signs of abdominal distention. At any time, the clinician may press the black button on the insufflation device to release excess air. At the end of the placement, the insufflation device should be disconnected from the feeding tube and the oral port should be closed.

12. Using console for placement.

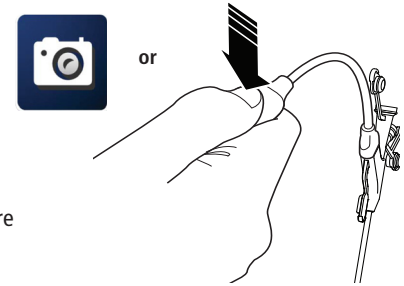
While inserting the Kangaroo feeding tube with IRIS technology, utilize the console screen to correctly identify anatomical markers during placement (see path images at right).

WARNING

Images of anatomical markers are for reference only. Refer to Kangaroo feeding tube with IRIS technology system training. Only a trained professional should use the system.



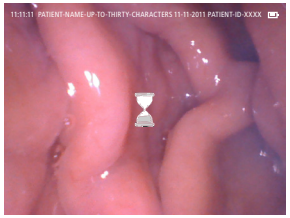
13. Capture images.



The system offers two ways to capture an image: using the interface cable or the console.

To capture an image using the interface cable:

- Press the button on the interface cable once to freeze the image during procedure
  – Once the image is frozen, it can be saved or discarded.
- To save the image, click the button on the interface cable once. An hourglass will appear on the screen while the system is saving the image.
  – To discard the image, click the button on the interface cable twice. Once the image has been discarded, the live feed will reappear on the console.



To capture an image using the console:

- Tapping on the camera icon on the display screen to freeze the image.
  – Once the image is frozen, it can be saved or discarded.
- Tapping the screen once while the image is frozen will cause the **Cancel** and **Complete** icons to appear.
  – Tap on the Done/Complete icon to save the image. An hourglass will appear on the screen while the system is saving the image.
- Tap on the Cancel icon to discard the image. Once the image has been discarded, the live feed will reappear on the console.

14. Ending procedure.

When the procedure is complete and the feeding tube has been placed properly, tap the green check mark.

A window will pop up requesting confirmation that the procedure is complete. If so, tap the green check mark again.

Disconnect the interface cable from the feeding tube and cover the electronic port.

Should the operator forget to end the procedure the system will automatically shut down after 120 minutes of the tube being powered on.

15. MR Information Card.

The MR information card provided within the instructions supplied with the Kangaroo feeding tube with IRIS technology is to be filled out and removed. The card is to be carried by the patient.

16. Confirm placement.

Confirm feeding tube position per institutional protocol. Supportive confirmation includes auscultation of the upper left quadrant during injection of air using a syringe and aspiration of gastric contents. If stylet is used, placement confirmation may be confirmed with a stylet secured within the tube. These tubes are equipped with a radiopaque material for facilitating radiological (X-ray or fluoroscopic) confirmation.

If there is uncertainty of the tube's distal location after institutional placement verification methods have been performed, confirmation by X-ray should be considered.

Stylet must be removed before commencement of enteral nutrition delivery.Safely dispose of all supplies according to the policy of your facility. The interface cable is re-usable, do not dispose.

CAUTION
Disconnect the feeding tube from the interface cable prior to feedings.

17. View captured images.

In the main menu, tap the folder menu icon. The folder menu will appear, displaying patient folders. Patient folders are named using their name, date of birth, and ID number. The patient folder holds all images captured during the procedure.

Double tap the desired patient folder to view a list of images stored within.

Double tapping on one of the images will display it on the screen.

18. Export images to USB.

Images can be exported to a USB flash drive and opened on another computer.

Plug the USB flash drive into the port on the side of the console.

Then, tap the box on the left of the image(s) to be exported. Tapping the box at the left of the folder selects all images.

Tap the USB icon.

A pop-up screen will ask which USB port the USB flash drive is plugged into. Confirm the appropriate drive and press the check mark.

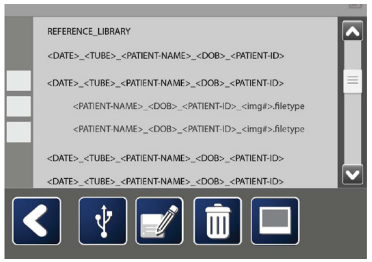
If only one USB is connected, the console will highlight that option.

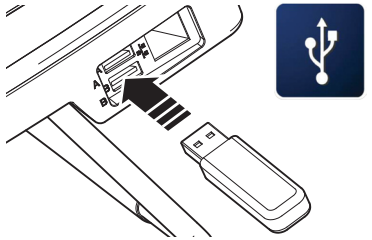
For privacy purposes, a password has been created by an administrator. The password will be required in order to view the images on computer.

Note: Passwords are in full upper-case. When using a computer, be sure to use all upper-case letters.

After the files are exported, disconnect the USB flash drive.

Use WinZip™* or 7-Zip to open the files. It is considered best practice to





CAUTION
Passwords are case-sensitive. Use upper-case letters when entering the password on the computer.
Verify USB devices used with this equipment are free of software viruses and other malicious software.

Reconnecting

Reconnecting the console and interface cable to the Kangaroo Feeding Tube with IRIS Technology:

A console used to place a feeding tube will retain the memory of which patient is associated to that tube. By re-connecting to the same feeding tube, the console will recognize it and ask for confirmation that the patient data is correct.

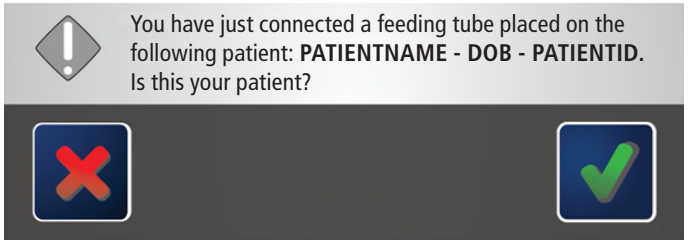
Note: Only the console used during the placement procedure will recognize the feeding tube and associated patient information. If a different console is connected to a pre-placed tube, entering the patient's information is required.

Power on and reconnect:

Power console on and enter login name and password.

Connect console to interface cable.

Connect interface cable to pre-placed Kangaroo feeding tube with IRIS technology.



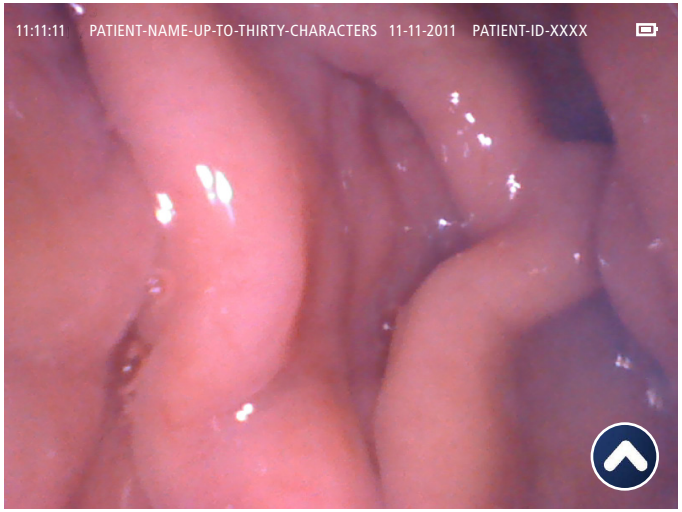
Confirm patient information:

A screen will pop up with the recognized patient information. Tap the check mark to confirm the information is correct.

If the information is incorrect, tap the "x" to go back to the main menu screen.

Focus on procedure screen:

The console will display the procedure screen with a live-feed from the camera on the end of the enteral feeding tube. Refer to parts section to order stylets.



Section IV: Cleaning, Charging, and Storage

General Console and Power Cord Cleaning Directions

Cleaning should be performed as needed.

WARNING

If any of the follow events occur, **do not use** the console or power cord until it has been properly cleaned and serviced by personnel trained in servicing these devices:

- wetting of the console's power cord or leakage into the interior during cleaning.
- spillage of large amounts of liquids onto the console exterior, or any spillage onto the power cord.

CAUTION

Failure to follow the cleaning procedures described herein could result in hazard to users. As with any AC powered electrical device, care must be taken to prevent liquid from entering the console to avoid electrical shock hazard, fire hazard, or damage to electrical components.

Disconnect console from AC power source before cleaning. After cleaning, do not connect to AC power source until console and power cord are thoroughly dry.

Do not immerse console or power cord in water or other cleaning solution; clean using a damp (not wet) cloth or sponge.

Cleaning of the console and cord must be performed as follows:

Use mild detergent for general cleaning.

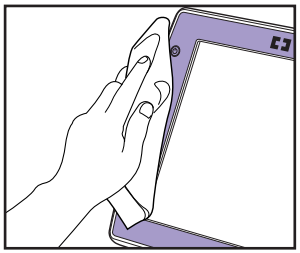
If necessary, the device may be cleaned with a 0.5% bleach mixture, or Clorox™* germicidal wipes. However, repeated cleaning with this solution can damage the plastic device case.

Isopropyl alcohol, applied with a damp (not wet) cotton swab, may be used for cleaning difficult-to-reach areas, however, it should be used sparingly because repeated cleaning may damage the case.

Do not use strong cleaners such as Spray-Nine™*, Phisohex™*, Hibiclens™*, or Vesta-Syde™* because damage to the device housing can result.

Directions for cleaning console:

- Refer to general cleaning directions above before starting.
- Clean outside surface with a damp (not wet) cloth or sponge and keep console in upright position as much as possible.
- Avoid excess moisture near mounting clamp area.
- Do not allow cleaning solution to enter the vertical vents in the housing, underneath the handle.



Directions for cleaning power cord:

- Unless soiling is observed, the power cord should not be cleaned.
- Refer to general cleaning directions above before starting.
- If cleaning of the power cord is necessary, unplug from outlet and wipe the exterior surfaces of the wall plug with a cloth dampened with isopropyl alcohol.

CAUTION

Avoid exposing power cord to excess moisture, as this can lead to an electrical shock or fire hazard.

Battery and Storage

Charging:

Between uses the console with the battery should be plugged into AC power to keep it at full charge. Charging stations and extra batteries are optional accessories. When using a charging station, refer to the instructions for use provided in the charging station packaging.

Battery:

The console has a replaceable rechargeable battery. It is also recommended that the battery charge be "topped off" before battery-only operation is utilized. The battery pack will charge continuously whenever the device is plugged into a wall outlet, including during normal use of the device with AC power.

Battery level indicator:

In the upper right corner of the screen is a battery icon.

This icon changes to reflect the amount of battery life remaining until recharging is needed. The icon will also show when the console is connected to an AC power outlet.

Left to right the symbols show 1) <10% 2) 10%-25% 3) 26%-50% 4) 51%-75% 5) 76%-100% 6) charging, 7) communication error, 8) missing battery.

When the console battery has 10% capacity left a low battery warning screen will appear. Tap the check mark and connect the console to an AC outlet using the removable power cord.

If the battery is very low, a warning screen will appear and the console will shut off. Plug the console in to charge the battery.

Storage requirements:

Store in environments of 0°C to +50°C and relative humidity of 15% to 85% (non-condensing).

Store the console away from direct sunlight, heat sources, and dust; in particular, do not expose the console to direct sunlight for long periods of time. Remove battery from console to preserve longevity. When using the mounting clamp, the console must be removed from the pole prior to removing the battery.

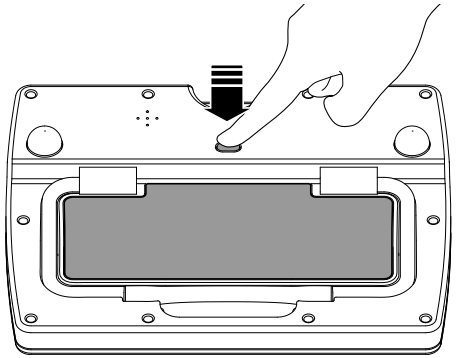
Removing the battery:

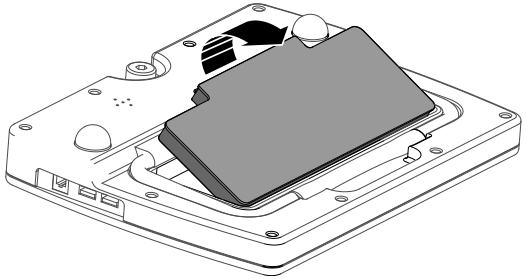
The battery can be easily removed, and replaced if necessary, by the user.

When the console is not in use for extended periods of time, removing the battery and storing separately can help maintain the battery's longevity.

Press the battery release button to pop one side of the battery out. Then, lift the battery off the console and place in proper storage.

Do not attempt to remove the battery while the console is attached to a pole.





Section V: User Interface Features

On Screen Keyboard

The on screen keyboard will be displayed when typing is necessary.
Use the keyboard to enter text, such as a login name, or to annotate images.

How to use the keyboard:

To enter text:

Tap a text field, such as a login name or password. Then, tap on the letters on the keyboard to type. Text will always be written in uppercase.

To edit text:

Tap the text field and use the arrow keys to navigate to the desired text location.

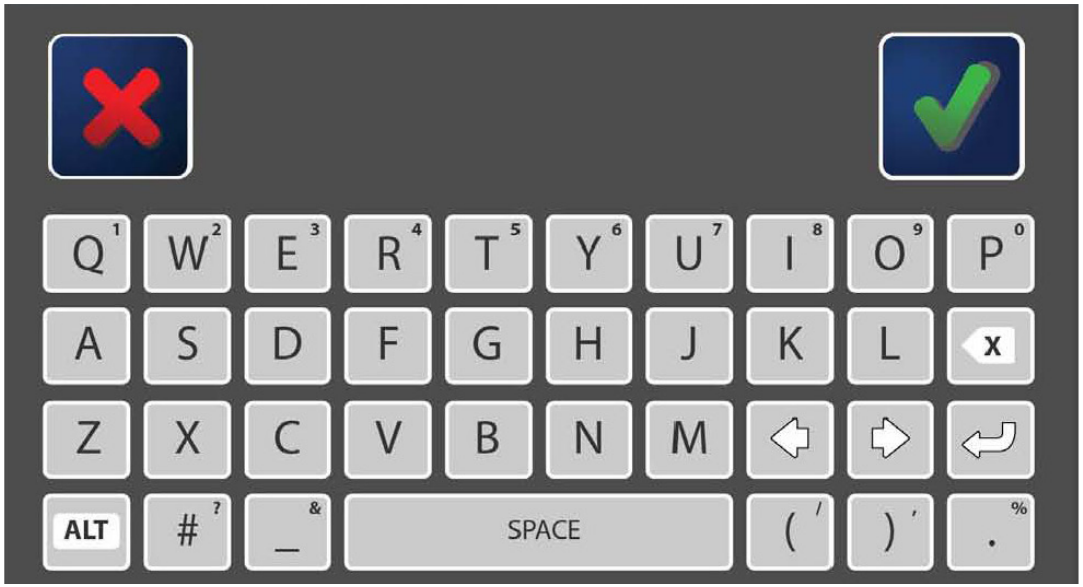
To enter numbers or secondary symbols:

Press and release the ALT key. Tap the key(s) that contains the desired letter, number, or symbol (displayed in the upper right corner of the key). Press and release the ALT key again to return to main keyboard.

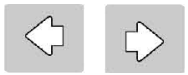
For example, to enter a login name of "64USER" press ALT, then 6, 4, then ALT again, followed by U, S, E, R.

Accept changes or cancel:

Tapping the check mark or "x" icons will either accept the entered text or cancel any changes and return to previous screen.



ALT key:
Enables alternate letter, symbol, or number keys.



Arrow keys:
Moves cursor left or right.

Return:
Moves cursor to next text field.

Delete text:
Deletes previously written text, letter by letter.

"X" icon:
Cancels any changes made and returns to previous screen.

Check mark icon:
Accepts changes made and advances to next screen.

Logging In and Automatic Log-Out

The console can only be used by approved individuals. A login name and password is required.

New users:

Only an administrator can set up a new user account.

Note: The original administrator login name is "ADMINISTRATOR", but other administrator accounts may be added.

Return users:

Using the on screen keyboard, enter the login name and password. Tap the check mark to confirm.

Automatic log-out:

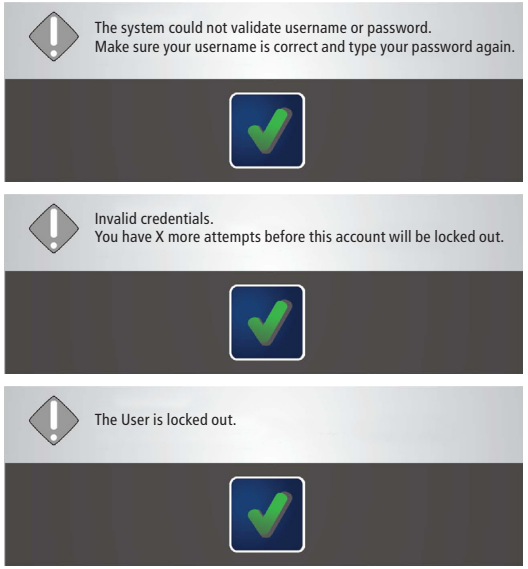
After a certain period of inactivity (where there is no user input to the console), the console will automatically log the user out. This inactivity time period is 5 minutes for operators and reviewers, and 10 minutes for administrators.

The automatic log-out will not occur during the procedure.

Wrong password for reviewer or operator account:

If a password is entered incorrectly, the system allows a user to attempt to login up to five times.

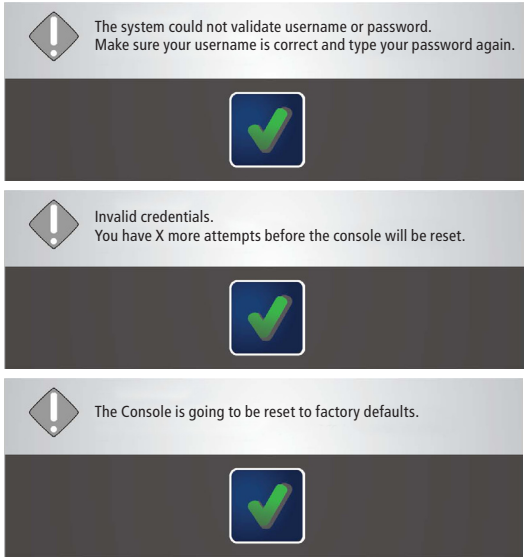
After the fifth attempt, the user's account is locked. To unlock the account, an administrator must reset the password from the settings menu.


The system could not validate username or password.
Make sure your username is correct and type your password again.
Invalid credentials.
You have X more attempts before this account will be locked out.
The User is locked out.

Wrong password for administrator account:

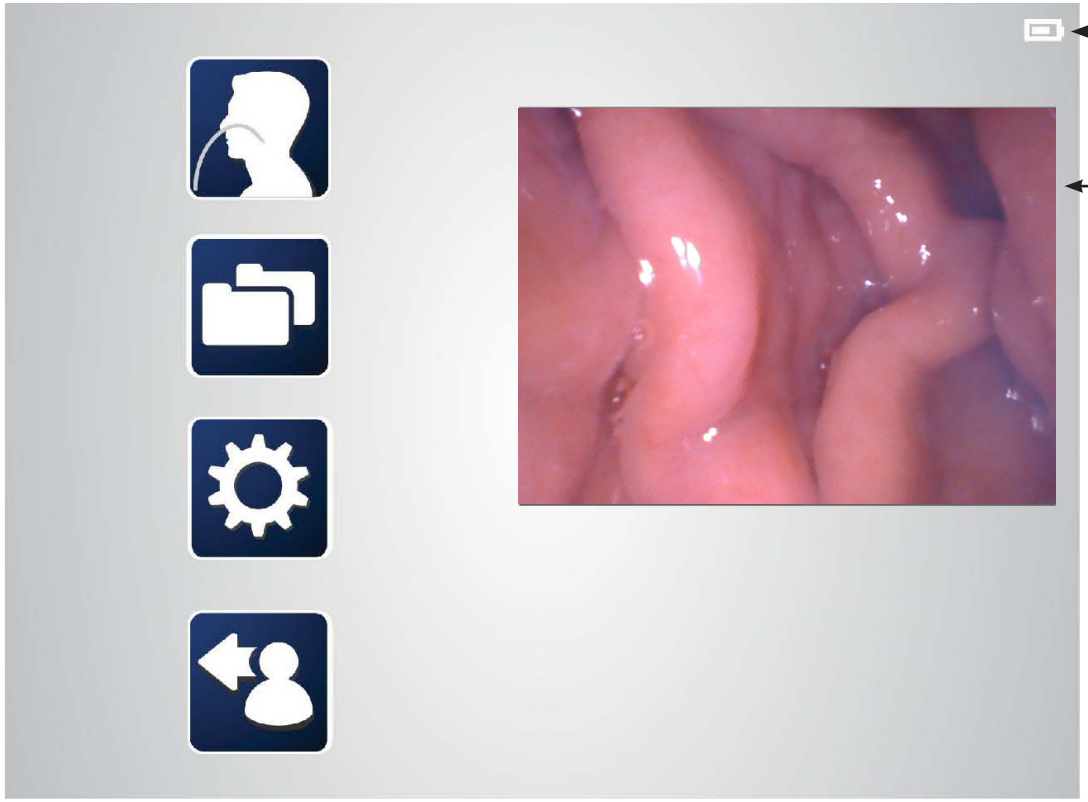
If a password for an administrator account is entered incorrectly, the system will allow up to five attempts.

After the fifth try, the console is reset to factory settings. All patient and user information will be lost.


The system could not validate username or password.
Make sure your username is correct and type your password again.
Invalid credentials.
You have X more attempts before the console will be reset.
The Console is going to be reset to factory defaults.

Main Menu

The main menu provides links to log out, settings, file management, and procedure Initiation. Clicking any of these icons brings you to those screens.



Procedure:

Use the procedure feature to launch the functional flow for entering patient information and procedure activities.

Settings menu:

The settings menu provides links to modify language, date/time, file formats, passwords, device options, and user settings.

Folders menu:

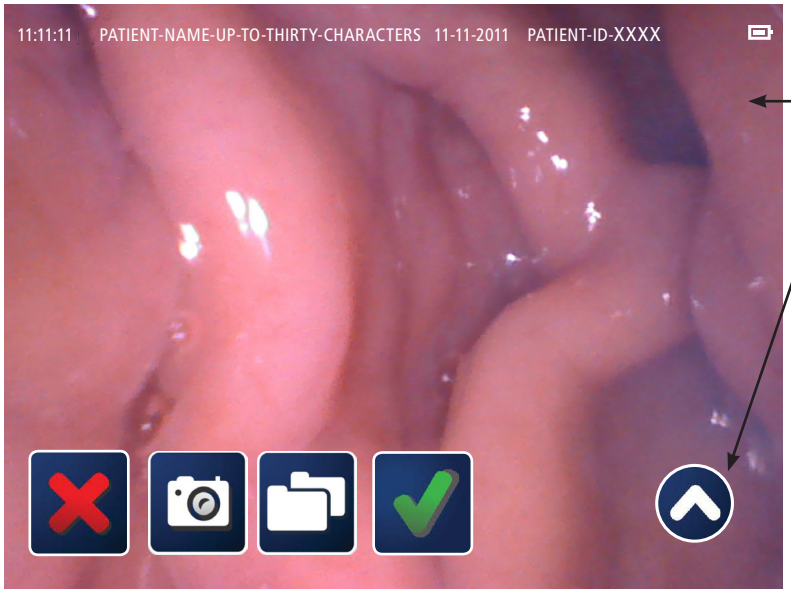
The folders menu launches the data browser of patient folders. Each folder contains images captured during the procedure.

Log out:

Clicking the log out icon ends the session.

Procedure

Use the Procedure feature to launch the functional flow for entering patient information and procedure activities.

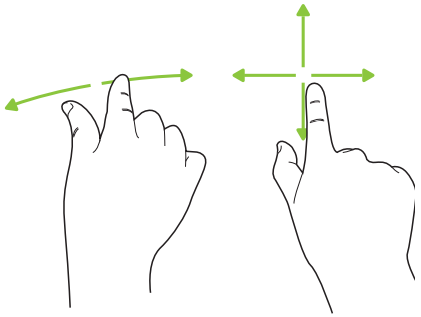


Zooming in/out, panning the image:

While touching the screen with two fingers, slide the fingers away from each other to zoom in.

Pan the screen by touching with one finger and dragging along the screen.

To zoom out, touch the screen with two fingers and slide them towards each other.



Cancel:
Cancel procedure. System will request cancellation confirmation.

Capture image:
Tap on the camera to capture an image from the live feed.

Patient folders:
Displays all patient folders. Each folder contains images captured during the placement procedure.

Patient file:
Icon appears after capturing an image. Tapping this icon opens patient's folder to show images.

Done/Complete:
When placement is complete, tapping on the check mark ends the placement procedure. System will request completion confirmation.

Hide icon tray:
Hides icon tray.

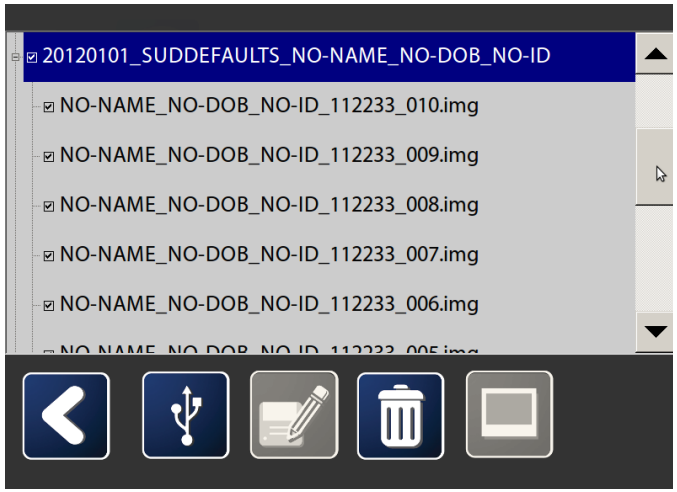
Show icon tray:
Show icon tray on screen.

Options for Viewing Patient Folders and Files

Patient folders and files:

Patient folders are auto-titled with the procedure date, feeding tube number, patient name, date of birth and patient identification. Select a patient folder to view by tapping twice on it. All images are listed below the patient folder. Images can be viewed, exported, annotated, or deleted.

Note: Screens shown below show sample data as an example.



Save to USB:

Export image(s) to USB flash drive. Exported images are password protected to ensure patient privacy.

Rename image:

Rename a portion of the image.

Delete image(s):

Delete one or more images from the patient folder.

View image:

View image in full screen.

Exporting Images to USB Flash Drive

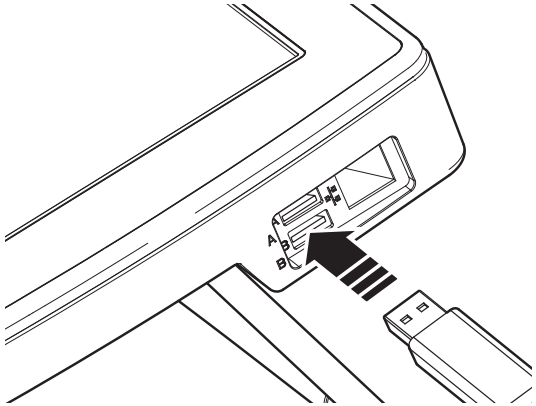
Save to USB:

Images can be exported to a USB flash drive and opened on another computer.

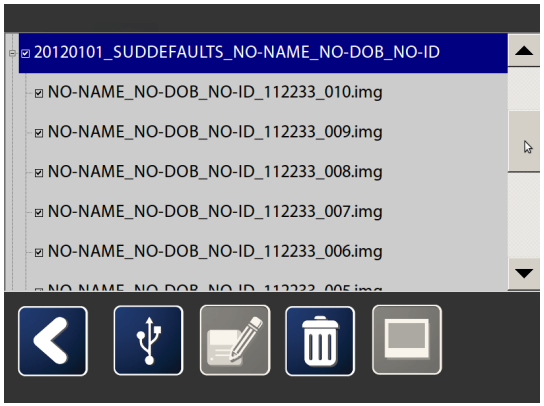
CAUTION

Verify USB devices used with this equipment are free of software viruses and other malicious software.

Start by plugging the USB flash drive into the port on the side of the console.



Then, tap the box on the left of the image(s) to be exported. Tapping the box at the left of the folder selects all images. Images can only be exported from one patient folder at a time.



Tap the USB icon. A screen will pop up asking which USB port to save to. Confirm and tap the check mark.

For privacy purposes, a password has been created by an administrator. The password will be required to view the images on another computer.

Note: Passwords are in full upper-case. When using a computer, be sure to use upper-case letters.

After the files are exported, disconnect the USB flash drive.

Opening Images from USB Flash Drive

Opening on a computer:

Images exported from the console can be opened on a computer and saved into a patient folder. The console will encrypt all files using a Zip file format before exporting them onto a USB drive. To open the images on a computer, the correct password must be entered.

Extracting and decoding files:

There are multiple Zip encoders/decoders. Use whichever the facility protocol states. Instructions for WinZip are shown here as an example.

First, start by opening WinZip.

Note: If the file is opened from WinZip without being extracted, it has not been decrypted. You will have to reenter the encryption password to open it again later.

Select the file, then click the "Extract" icon.

Next, choose the directory for the extracted folder. Then, click the "Extract" button.

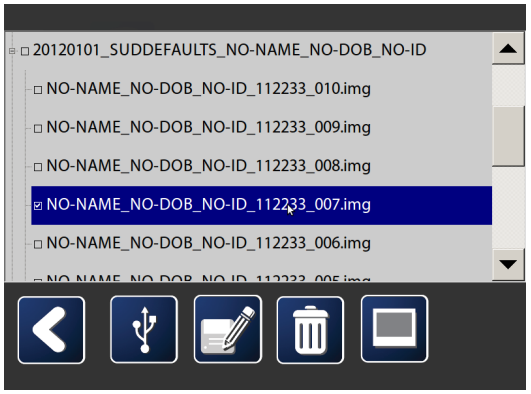
Enter the password, making sure to only use uppercase letters. The images should then be decrypted and able to be opened.

Rename Image

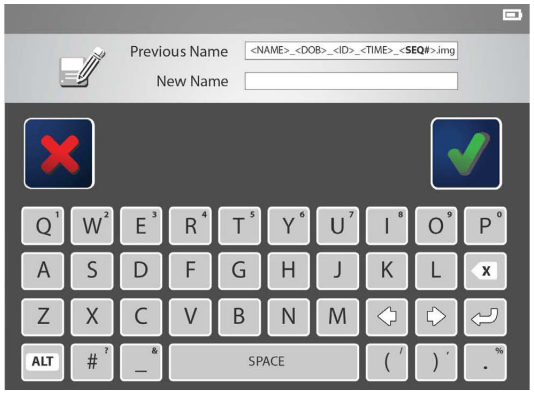
Renaming an image:

Captured images are automatically titled with the patient's name, date of birth, identification number, and an image number. The image numbers are created sequentially as they are captured.

When renaming an image, only the portion with the image number can be changed.



Select the image to rename by tapping on it, then tapping on the rename image icon. A screen will pop up. Using the text field, enter the new name for the image. Press the check mark when finished.



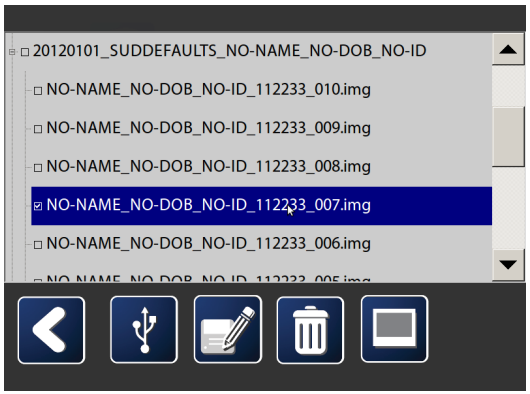
Note: Images can only have letters or numbers in the name; symbols will not work.

Only one image can be renamed at a time.

Delete Image(s)

Delete image(s):

Select one or more images to delete by tapping on the boxes to the left. Then, tap the delete icon.

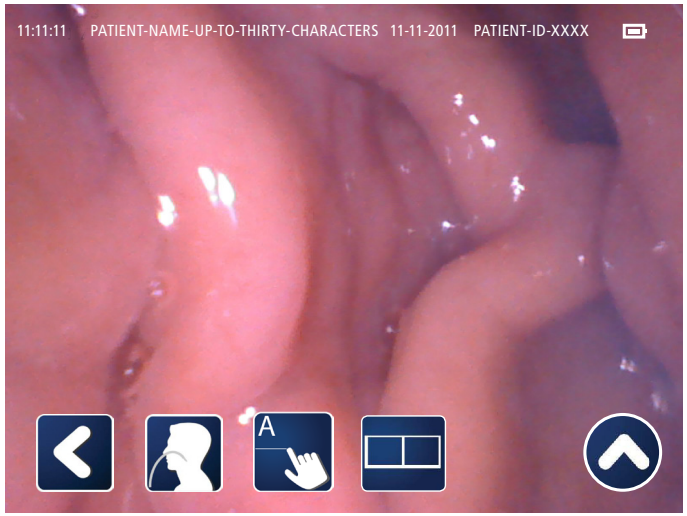


The system will require confirmation before deleting. Tap the check mark to confirm.

Viewing Captured Images

View image:

When viewing a captured image there is an option to annotate, view in split screen, and return to the procedure (live feed from camera).

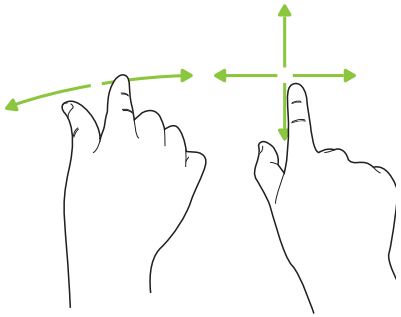


Zooming in/out, panning the image:

While touching the screen with two fingers, slide the fingers away from each other to zoom in.

Pan the screen by touching with one finger and dragging along the screen. Panning is only active when zoomed in.

To zoom out, touch the screen with two fingers and slide them towards each other.



Procedure:

If not currently in the procedure process, this icon will appear. Tapping this icon opens the procedure screen.

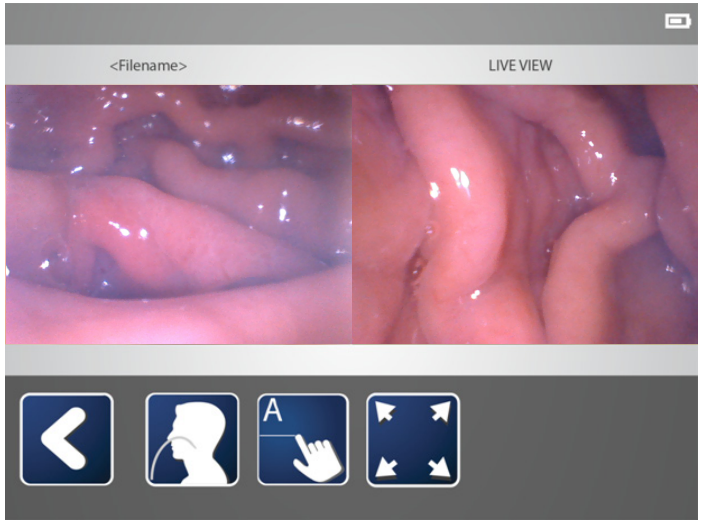
Annotate image:

Select an image to annotate by clicking the box to the left. Then, tap the annotation icon.

For detailed information on annotating images, see the annotating images section.

Split view:

Viewing in split screen will show the captured image on the left and the live view from the camera on the right side.



Full screen view:

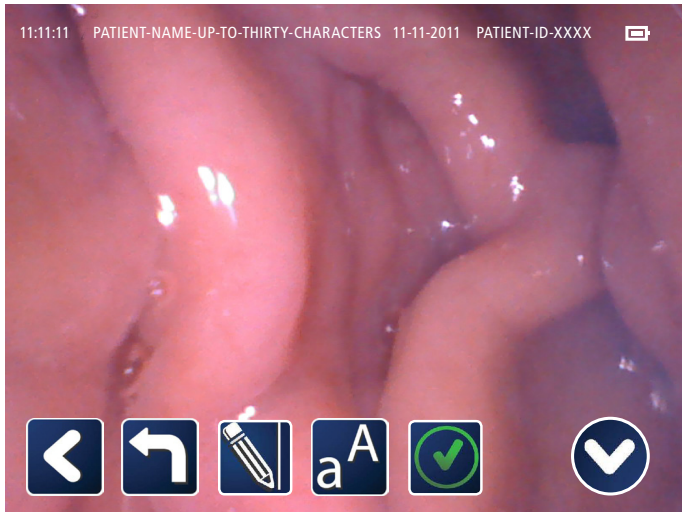
To switch to full screen view, tap this icon.

Annotating Images

Annotating images:

Tap on the annotate icon to bring up a icon tray with annotation options. Tap the icons to add text, lines, or undo actions. A reviewer can view the images and confirm that they have reviewed them. Further annotation of images is not allowed after a still image is reviewed.

Note: Annotation is not possible when image is zoomed in.

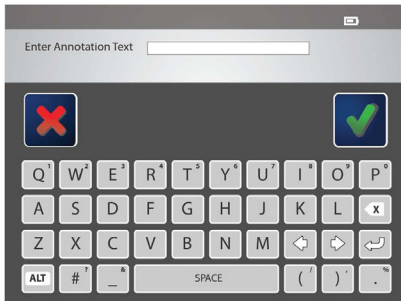


Draw a line on the image:

Tap on the icon. Then, touch the screen where the line should start. Touch the screen again at the point where the line should end.

Add text to the image:

Select the icon, then tap on the screen where the text should be. A list of anatomical marker labels will appear. At the bottom of the list is an option to enter free text. With free text, a keyboard will appear. Enter the text, then press the check mark. Confirmation will be required to save the changes.



Review an image (reviewer only):

Reviewing an image places a time stamp with the reviewer's login name and the time.

Note: Once a reviewer confirms the review by tapping the checkmark, no further annotations can be made.

Undo:

Undo up to twenty previous actions. You can "undo" a review in order to continue making annotations.

Operator and Reviewer Settings

Settings:

Operators and reviewers can change the language preference and their password from the settings menu.

The current settings for the console are shown on the screen. The Device Version shown indicates the software version currently on the console.

Change language:

Tapping on the language icon displays a screen giving optional language preferences. Tap once on the preferred language, then tap the check mark to save changes.

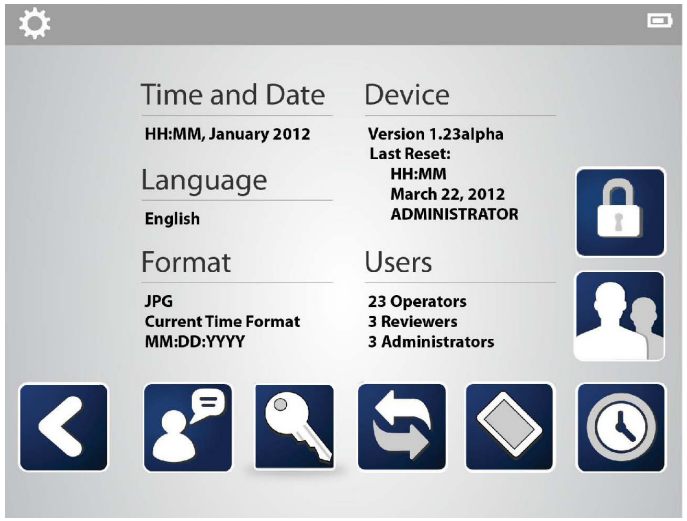
Change password:

To change the account password, tap on the key icon. Use the keyboard to enter a new password, then repeat the password in the second text field. Tapping the check mark saves the changes.

Administrator Settings

Settings:
Administrators can make changes to the time, date, language, image format, user information, and update the device.

The current settings for the console are shown on the screen. The Device Version shown indicates the software version currently on the console.



Change language:
Tapping on the language icon displays a screen giving optional language preferences. Tap once on the preferred language, then tap the check mark to save changes.

Change password:
To change the account password, tap on the key icon. Use the keyboard to enter a new password, then repeat the password in the second text field. Tapping the check mark saves the changes.

Format images:
Choose between exporting images as a .bmp or .jpg. Change the date format to the preferred order. Edit the way time is displayed during placement.

Device:
Erase patient data, update the device software, or reset the device back to factory settings.

Set or change date and time:
Use the touchscreen to select the time and date. If English language is currently selected on the console, select preferred time format (24 hours or 12 hours), then tap the check mark to save changes.

User groups:
Add or change user passwords.

Encryption password:
Change password used to decrypt/open patient images on a computer. Passwords will be in all uppercase letters and are case sensitive.

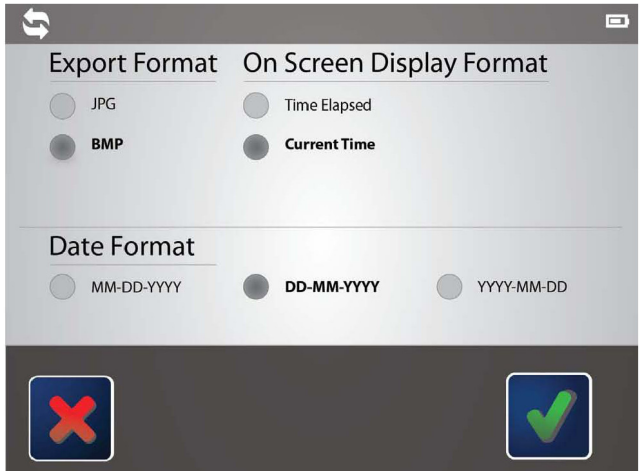
Changing Date, Time, Formatting, Language, and Device Settings

Set or change date and time:

Use the touch screen to select the time and date. If English language is currently selected on the console, select preferred time format (24 hours or 12 hours), then tap the check mark to save changes.

Format images:

Choose between exporting images as a .bmp or .jpg. Change the date format to the preferred order. Edit the way time is displayed during placement.

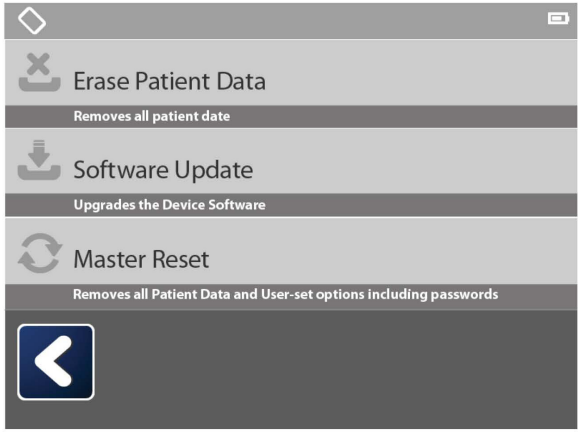


Change language:

Tapping on the language icon displays a screen giving optional language preferences. Tap once on the preferred language, then tap the check mark to save changes.

Device:

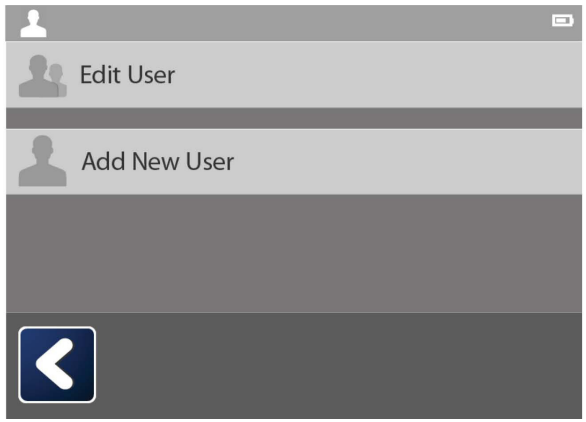
Tap on the "Erase Patient Data" block to permanently remove all stored patient information and captured images (recommended if sending console for maintenance). The "Software Update" upgrades the device to the latest version. Tapping "Master Reset" removes all data and restores to factory settings.


Erase Patient Data
Removes all patient date
Software Update
Upgrades the Device Software
Master Reset
Removes all Patient Data and User-set options including passwords

Adding and Editing Users

User groups:

Select the user groups icon to add a user or edit a user's information.



Operator:

Can access the system to perform procedures and annotate.

Reviewer:

Can access the system to perform procedures, annotate, and review any images edited by operators.

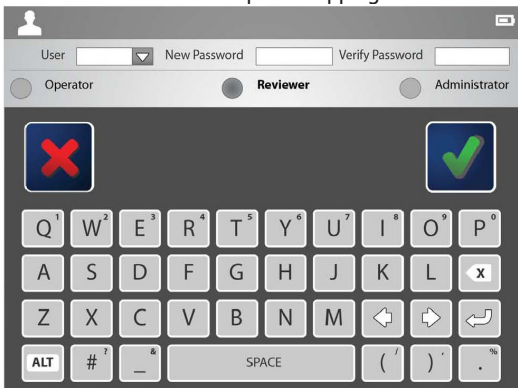
Administrator:

Can access any part of the system, perform procedures, annotate, remove patient information, add or edit users, update the software, and reset the device to factory settings.

Edit user type/password:

Select a pre-existing user in the top left corner. To change the user's password, enter the new password and then verify it by entering it again. Tap the check mark to save changes.

To change the user's control (operator, reviewer, or administrator) simply tap on the circle next to the desired option. Tapping the check mark will save changes.

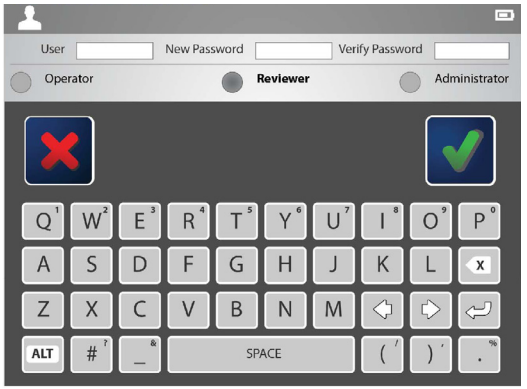


Add user:

Add a user by typing in the login name, desired password, and the user's control type (operator, reviewer, or administrator).

Tapping the check mark will save changes.

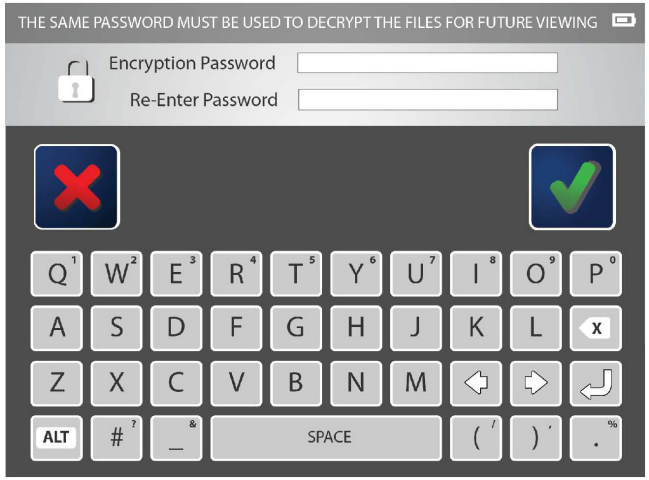
Note: Login names "ADMINISTRATOR" and "MAINTAINER" are in use, those user names cannot be duplicated.



Creating and Editing Encryption Password

Encryption password:

Select the encryption password icon to edit the password used to open patient images on a computer. The password created will be needed to open any files exported from this console. The same password will be used for any files exported.


THE SAME PASSWORD MUST BE USED TO DECRYPT THE FILES FOR FUTURE VIEWING
Encryption Password
Re-Enter Password
Q W E R T Y U I O P
A S D F G H J K L
Z X C V B N M
ALT
SPACE

Tap on the first text field to enter the desired password. Then, re-enter the password in the text field below. When satisfied, touch the check mark to save the changes.

Note: The password is case-sensitive and will be in all upper-case.

Icon Glossary

Cancel

Take picture

File

Done / Complete

Hide icon tray

Show icon tray

Add text

Annotate image

Return to previous screen

Delete

Device

Encryption password

Full screen view

Language

Draw line

Log out

Password

Procedure

Reset console

Review image

Save to USB flash drive

Set time

Settings

Undo action

Update software

User groups

User

Wait

Split view

View image

Erase patient data

Folders

Format

Rename

Section VI: Additional Kangaroo Feeding Tube with IRIS Technology Information

Section VI: Additional Kangaroo Feeding Tube with IRIS Technology Information

Order information - To purchase any of these accessories, contact your Covidien customer service representative.

Accessories for Kangaroo Feeding Tube with IRIS Technology

Kangaroo Console:

Item Code	Order Information
386100	1 each/case

Kangaroo Feeding Tube with IRIS Technology:

Item Code	Product Size	Order Information
460836	8 Fr/Ch (2.7 mm) x 36″ (91 cm)	5 each/case
460843	8 Fr/Ch (2.7 mm) x 43″ (109 cm)	5 each/case
460855	8 Fr/Ch (2.7 mm) x 55″ (140 cm)	5 each/case
461036	10 Fr/Ch (3.3 mm) x 36″ (91 cm)	5 each/case
461043	10 Fr/Ch (3.3 mm) x 43″ (109 cm)	5 each/case
461055	10 Fr/Ch (3.3 mm) x 55″ (140 cm)	5 each/case
461236	12 Fr/Ch (4.0 mm) x 36″ (91 cm)	5 each/case
461243	12 Fr/Ch (4.0 mm) x 43″ (109 cm)	5 each/case
461255	12 Fr/Ch (4.0 mm) x 55″ (140 cm)	5 each/case

Kangaroo™ Replacement Stylets for use with Kangaroo Feeding Tube with IRIS Technology:

Item Code	Product Descriptor	Size	Order Information
468036	8 Fr/Ch (2.7 mm) Replacement Stylet	36" (91 cm)	5 each/case
468043	8 Fr/Ch (2.7 mm) Replacement Stylet	43" (109 cm)	5 each/case
468055	8 Fr/Ch (2.7 mm) Replacement Stylet	55" (140 cm)	5 each/case
460036	10 Fr/Ch (3.3 mm) Replacement Stylet	36" (91 cm)	5 each/case
460043	10 Fr/Ch (3.3 mm) Replacement Stylet	43" (109 cm)	5 each/case
460055	10 Fr/Ch (3.3 mm) Replacement Stylet	55" (140 cm)	5 each/case
462036	12 Fr/Ch (4.0 mm) Replacement Stylet	36″ (91 cm)	5 each/case
462043	12 Fr/Ch (4.0 mm) Replacement Stylet	43″ (109 cm)	5 each/case
462055	12 Fr/Ch (4.0 mm) Replacement Stylet	55″ (140 cm)	5 each/case

Kangaroo™ System Accessories for use with Kangaroo Feeding Tube with IRIS Technology:

Item Code	Product Descriptor	Order Information
388101	Power Adapter	1 each/case
388102	Replacement Battery	1 each/case
388103	Interface Cable	1 each/case
388104	Mounting Clamp	1 each/case
388105	Insufflation Device	5 each/case
388107	Battery Charging Station	1 each/case
388106	Mounting Cart	1 each/case
388108	Carrying Case	1 each/case

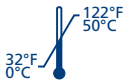
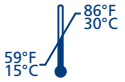
Section VI: Additional Kangaroo Feeding Tube with IRIS Technology Information

Troubleshooting

Issue	Actions
Console screen stops working during procedure	1. Read all warnings and precautions prior to tube insertion. 2. Explain procedure to the conscious patient. Prepare supplies —oral tip syringe, feeding tube water, wipes, and stethoscope. 3. Position patient in accordance with facility protocol for feeding tube placement. 4. To estimate insertion depth, use the tube to measure the distance from the tip of the patient's nose to the earlobe and from the earlobe to the xiphoid process for gastric placement. Add approximately 10 (ten) inches (25 cm) for intestinal placement. Spontaneous transpyloric passage of the tip often occurs within 24 to 48 hours. 5. Passage of the feeding tube through the nasal passage into the stomach can be facilitated by using a stylet. 6. Activate the Hydromer coating on the tip of the tube by submerging the weight assembly in water for at least 5 seconds. 7. Choose the most patent nare and insert the feeding tube with the stylet (if the stylet is used). Once in place, do not manipulate or pull the stylet back and forth within the feeding tube. When the tube has reached the oropharynx encourage the patient to swallow. Giving sips of cool or room temperature water may assist the passage of the tube. 8. Confirm tube position per institutional protocol. Supportive confirmation includes auscultation of the upper left quadrant during injection of air using a syringe and aspiration of gastric contents. Placement confirmation may be confirmed with a stylet secured within the tube. These tubes are equipped with a radiopaque material for facilitating radiological (X-ray or fluoroscopic) confirmation. **Warning:** If there is uncertainty of the tube's distal location after institutional placement verification methods have been performed, confirmation by X-ray should be considered. 9. Once the tube position has been confirmed, the stylet is then removed by gentle traction. Tape the tube securely, avoiding pressure on the nares. 10. Disconnect the feeding tube from the interface cable prior to feedings. Enteral feedings may begin by filling the enteral feeding bag, purging the tubing of air, and connecting it to the feeding tube.
No live feed from camera	1. Check connections on both sides of the interface cable. Ensure that everything is plugged in correctly and securely. 2. Advance the feeding tube forward or backward a few inches. 3. If feeding tube tip is estimated to be in the stomach or small bowel, try insufflation, then flush tube with water using syringe. 4. If feeding tube is estimated to be located prior to the stomach or small bowel, remove, wipe, and try again. 5. If problem still persists, adhere to blind placement procedure.
Battery dies during placement	Confirm all components are securely and properly connected. Connect power adapter to console and AC outlet.
Console is not functioning	Press and hold the power button for 10 seconds. The console will shut down. Wait 30 seconds, then press the power button to turn it back on. If problem persists, check battery level.

Section VI: Additional Kangaroo Feeding Tube with IRIS Technology Information

Definition of Symbols

Symbol	Definition
	Non-sterile
	Not made with natural rubber latex
	Not made with Di(2-ethylhexyl)phthalate
	Identification of a substance that is not contained or present within the product or packaging.
	Single use only, do not re-use
Rx ONLY	Federal (USA) law restricts this device to sale by or on the order of a physician
	Caution, consult accompanying documents
	Consult instructions for use
	Follow instructions for use
MR Conditional	Indicates that the specific device poses no known hazards in a specified MR environment (specific field strength, spatial gradient, RF pulse limitations, and specific absorption rate).
MR Unsafe	Indicates the device would be unsafe in any MR environment.
	Store in temperatures between 0°C and 50°C, 15% to 85% (non-condensing)
	Store in temperatures between 15-30°C (59-86°F)

Symbol	Definition
	Keep away from sunlight
	Keep Dry
	Dispose of as Electrical and Electronic Waste
	Type BF protection against electrical shock
	Class II Equipment
IPX4	Protected against splashing water
	NRTL test mark performed for compliance; "Safety Tested"
	NRTL test mark performed for compliance; "Type Tested"
CE 0123	CE Mark
REF	Catalog number
	Manufacturer
	Date of manufacture
EC REP	Authorized representative in the European Community
SN	Serial Number

Table of Contents

Warranty

Limited warranty:

Covidien llc, warrants to the original purchaser ("Customer") that this product will be free of defects in materials and workmanship, under normal use, for one (1) year from the date of original purchase from Covidien or its authorized distributor. If this product does not operate as warranted above during the applicable warranty period, Covidien may, at its option and expense, replace the defective part or product with a comparable part or product, repair the defective part or product, or, if neither replacement nor repair is reasonably available, refund to Customer the purchase price for the defective part or product. Dated proof of original purchase will be required. Covidien does not assume any liability for loss arising from unauthorized repair, misuse, neglect, or accident.

Section VI: Additional Kangaroo Feeding Tube with IRIS Technology Information

Specifications

Console dimensions:

29.5 x 21.6 x 4 cm (11.6 x 8.5 x 1.57 in)

Console weight / mass:

4.95 lb / 2.24 kg

Console power:

Use AC adapter for wall outlet usage. Console operates on 15 VDC, 40 W. Use only Kangaroo feeding tube with IRIS technology console AC adapter.

AC power adapter:

The power supply is a part of the ME equipment. It is rated for continuous use.

Input Voltage: 100-240 VAC

Input Frequency: 50-60 Hz

Console battery:

New, fully charged Lithium Ion Battery Pack delivers approximately four hours of service before needing to be recharged

Rated Voltage: 11.IV DC

Rated Capacity: 3.7Ah (41.0Wh)

Console image output format:

Bitmap (BMP, uncompressed) or
JPEG (JPG, compressed) file format,
800 x 600 pixel resolution

Operating temperature, humidity and altitude:

10°C - 40°C, 15-85% R.H. non-condensing

Operating altitude for this system is 2000M or less

Storage and transport temperature and humidity:

0°C - 50° C, 15-85% R.H. non-condensing

Type of protection against electrical shock:

Class II, Internally-powered Equipment

Degree of protection against electrical shock:

Type BF

Please ensure device is plugged into an easily accessible outlet in case of emergency.

Degree of protection against ingress of fluids:

IPX4 (in a typical use configuration with all console port covers closed except for the power cable and interface cable covers both being open with those cables plugged in. See page 8 for cover information).

MRI Safety Information:

Items	MRI Information
Console with power accessories, interface cable, stylet, mounting clamp and carrying case	MR Unsafe
Kangaroo feeding tube with IRIS technology	MR Conditional

The Kangaroo feeding tube with IRIS technology was determined to be MR Conditional. **Do not** bring MR Unsafe items into the MRI scan room. This includes all components and accessories of the Kangaroo system (console, interface cables, stylet, etc.) other than the Kangaroo feeding tube with IRIS technology.

Non-clinical testing demonstrated that the Kangaroo feeding tube with IRIS technology is MR Conditional. A patient with this device can be scanned safely, immediately following positioning of this feeding tube under the following **MR Scan Conditions:**

- The stylet must be removed from the Kangaroo feeding tube with IRIS technology prior to permitting the patient to enter the MR system room to undergo an MRI examination
- Static magnetic field of 1.5 or 3.0 Tesla
- Maximum spatial gradient magnetic field of 3,700-gauss/cm (37 T/m)
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of <2 W/kg (Normal Operating Mode).

MRI-related heating:

Under MR Scan Conditions defined above, the Kangaroo feeding tube with IRIS technology is expected to produce a maximum temperature increase of 1.5°C after 15 minutes of continuous scanning.

These temperature changes will not pose a hazard to a human subject under the conditions indicated above.

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Kangaroo feeding tube with IRIS technology. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 10-mm relative to the size and shape of this device.

Applied part definition:

Per IEC 60601-1 3rd Edition, the applied part of this system is the Kangaroo feeding tube with IRIS technology.

Section VI: Additional Kangaroo Feeding Tube with IRIS Technology Information

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	14,108-mm^2	1,095-mm^2	12,655-mm^2	1,916-mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

USB ports:

The USB ports will support only USB flash drive and USB hard drives. Do not plug any other device into the USB ports.

Covers on console and tube:

Close the covers on the console ports for the tube, USB, and Ethernet when they are not in use to protect the console from spills and splashes.

Note: the Ethernet port is currently not enabled.

Close the electronic port on the feeding tube when it is not being used with the interface cable and console.

Maintenance and safety:

Do not open the console housing, as there are no user-serviceable parts inside. Opening may affect function of device and voids the warranty. To replace battery, see Section IV.

The console must be periodically tested to assure proper functioning and safety. The recommended service interval is at least once per year. To arrange for Covidien Factory Service in the US, call 1-800-448-0190. In Canada, please contact 1-877-664-8926. Outside of the US and Canada, please contact your local Customer Service for more information.

Specifications

Electrical Safety

The Kangaroo feeding tube with IRIS technology has been built and tested according IEC 60601 3ED 2005, ANSI/AAMI ES 60601-1:2005, CAN/CSA C22.2 No. 60601-1-08, IEC 60601-1-6:2010, IEC 60601-1-2 Ed. 3.0:2007 Standards.

The Kangaroo feeding tube with IRIS technology, when used with the console as a system is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.

Electromagnetic Conformity Declaration.

Emissions Tests	Compliance	Electromagnetic Environment - Guidance
RF emissions (CISPR 11:2010)	Group 1	See guidance comments for emissions tests in the tables on the following pages.
RF emissions (CISPR 11:2010)	Class A	
Harmonic emissions (EN 60601-3-2:2009)	Class A	
Voltage Fluctuations / flicker emissions (EN61000-3-3:2008)	Complies	
Immunity Tests	**Compliance**	**Electromagnetic Environment - Guidance**
Radiated Disturbance Immunity (EN60601-1-2:2007 / IEC 61000-4-3:2010)	Complies	See guidance comments for immunity tests in the tables on the following pages.
Conducted Disturbance Immunity (EN60601-1-2:2007 / IEC 61000-4-6:2008)	Complies	
Power Frequency Magnetic Field Immunity (EN606010102:2007 / IEC 61000-4-8:2009)	Complies	
Voltage Dips and Sags Immunity (EN606010102:2007 / IEC 61000-4-11:2011)	Complies	
Electrical Fast Transient / Bursts Immunity (EN606010102:2007 / IEC 61000-4-4:2011)	Complies	
Electrostatic Discharge Immunity (EN606010102:2007 / IEC 61000-4-2:2008)	Complies	
Surge Immunity (EN60601-1-2:2007 / IEC 61000-4-5:2005)	Complies	

For any questions please contact Covidien Customer Service at 1-800-962-9888, or your local sales representative.

Section VI: Additional Kangaroo Feeding Tube with IRIS Technology Information

Guidance and manufacturer's declaration – electromagnetic emission		
The Kangaroo feeding tube with IRIS technology, when used with the console as a system is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Kangaroo feeding tube with IRIS technology, when used with the console as a system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	The Kangaroo feeding tube with IRIS technology, when used with the console as a system is suitable for use in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 6100-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 6100-3-3	Complies	

Section VI: Additional Kangaroo Feeding Tube with IRIS Technology Information

Guidance and manufacturer's declaration – electromagnetic immunity			
The Kangaroo feeding tube with IRIS technology, when used with the console as a system is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnet environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines 1kV for signal line	±2 kV for power supply lines 1kV for signal line	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in UT) for 0.5 cycle 40% U_T (60% dip in UT) for 5 cycles 70% U_T (30% dip in UT) for 25 cycles <5% U_T (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Kangaroo feeding tube with IRIS technology, when used with the console as a system requires continued operation during power mains interruptions, it is recommended that it be powered from an uninterruptable power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/min	3A/min	Mains power quality should be that of a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Section VI: Additional Kangaroo Feeding Tube with IRIS Technology Information

Guidance and manufacturer's declaration – electromagnetic immunity			
The Kangaroo feeding tube with IRIS technology, when used with the console as a system is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnet environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Kangaroo feeding tube with IRIS technology, when used with the console as a system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency transmitter. Recommended separation distance d = [3.5 / V 1] √P d = [3.5 / E 1] √P 80 MHz to 800 MHz d = [7.0 / E 1] √P 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distances in meters (m). Field strengths from fixed RF transmitters, as determined by an electronic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Kangaroo feeding tube with IRIS technology, when used with the console as a system is used exceeds the applicable RF compliance level above, the Kangaroo feeding tube with IRIS technology, when used with the console as a system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Kangaroo feeding tube with IRIS technology, when used with the console as a system. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Section VI: Additional Kangaroo Feeding Tube with IRIS Technology Information

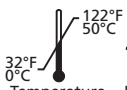
Recommended separation distances between portable and mobile RF communications equipment and the Kangaroo feeding tube with IRIS technology, when used with the console as a system			
The Kangaroo feeding tube with IRIS technology, when used with the console as a system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Kangaroo feeding tube with IRIS technology, when used with the console as a system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = [3.5 / V1] \sqrt{P}$	80 MHz to 800 MHz $d = [3.5 / E1] \sqrt{P}$	800 MHz to 2.5 GHz $d = [7.0 / E1] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Rx ONLY

Follow instructions for use. Symbol appears blue on device.

MR Unsafe – an item that is known to pose hazards in all MR environments.

MR Unsafe



Temperature limitations

Keep dry

CE

COVIDIEN

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Covidien llc, 15 Hampshire Street,
Mansfield, MA 02048 USA.
EC REP Covidien Ireland Limited, IDA Business & Technology Park, Tullamore.

www.covidien.com [T] 1-800-962-9888

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